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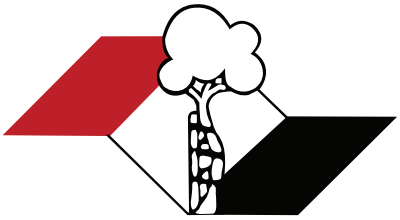

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Acta Ortopédica Brasileira

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Oxotron

loxoprofeno sódico

A NOVA OPÇÃO NO TRATAMENTO ANTI-INFLAMATÓRIO.[1,2]

RÁPIDO INÍCIO DE AÇÃO[2,3]

Início de ação a partir de 15 minutos[2]

- **Atividade preferencial sobre a COX-2[4,5]**
- **Fármaco seguro[4,6]**
- **Boa tolerabilidade[4]**
- **Tão eficaz quanto celecoxibe, ibuprofeno e naproxeno na redução da dor e inflamação em pacientes com dor pós-operatória, osteoartrite e ombro congelado[7]**

Referências Bibliográficas: 1) BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/rconsulta_produto_detalhe.asp>. Acesso em: Out. 2016. 2) Bula do produto OXOTRON: comprimidos. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 3) LANDIM, E. et al. Loxoprofeno sódico no tratamento das lombalgias. Revisão bibliográfica. RBM, v. 57, n. 4, p. 298-302, 2000. 4) DUTRA, F.G.; ENGELKE, F. O uso do loxoprofeno sódico* nos processos inflamatórios comuns em reumatologia e ortopedia: Estudo colaborativo. RBM, v. 58, n. 1/2, p. 39-48, 2001. 5) MARONE, S.; ENGELKE, F. Loxoprofeno sódico no tratamento complementar das infecções agudas das vias aéreas superiores: Estudo colaborativo. RBM, v. 58, n. 3, p. 171-178, 2001. 6) LEDERMAN, R.; GUIMARÃES, S.; VERZTMAN, J.F. Eficácia clínica e segurança do loxoprofeno sódico (Loxonin®) no tratamento da gonartrose. RMB, v. 58, v. 4, p. 263-271, 2001. 7) GREIG, S.L.; GARNOCK-JONES, K.P. Loxoprofen: A review in pain and inflammation. Clin Drug Investig, v. 36, n. 9, p. 771-81, 2016.

OXOTRON É UM MEDICAMENTO. DURANTE SEU USO, NÃO DIRIJA VEÍCULOS OU OPERE MÁQUINAS, POIS SUA AGILIDADE E ATENÇÃO PODEM ESTAR PREJUDICADAS

Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais.INTERAÇÕES MEDICAMENTOSAS: Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos.

Oxotron. Loxoprofeno sódico. MEDICAMENTO SIMILAR EQUIVALENTE AO MEDICAMENTO DE REFERÊNCIA. 60 mg. Comprimido. USO ORAL. USO ADULTO. Oxotron. Loxoprofeno sódico. APRESENTAÇÕES. Comprimidos 60 mg: embalagens com 8, 15 ou 30 comprimidos. USO ORAL. USO ADULTO. COMPOSIÇÃO. Cada comprimido de Oxotron contém: Loxoprofeno sódico anidro (como loxoprofeno sódico di-hidratado) 60 mg. Excipientes: lactose monoidratada, estearato de magnésio, hiprolose de baixa substituição, óxido férrico vermelho. INFORMAÇÕES TÉCNICAS AOS PROFISSIONAIS DE SAÚDE. **INDICAÇÕES.** Oxotron está indicado como anti-inflamatório e analgésico no tratamento de artrite reumatoide, osteoartrite, periartrite escapuloumeral, processos inflamatórios osteomusculares do pescoço, ombro, braço e lombalgias; como analgésico e anti-inflamatório em pós-cirurgia, pós-traumatismo e pós-exodontia; como analgésico anti-inflamatório e antitérmico em processos inflamatórios agudos do trato respiratório superior (acompanhados ou não de bronquite aguda). **CONTRAINDICAÇÕES**. Oxotron está contraindicado em: Crianças e jovens menores de 18 anos de idade, gestantes no último trimestre da gravidez e durante o período de lactação; pessoas que apresentaram reações de hipersensibilidade ao loxoprofeno ou a qualquer um dos componentes da fórmula; portadores de úlcera péptica, graves distúrbios hematológicos, hepáticos ou renais; portadores de disfunções cardíacas graves; indivíduos com asma induzida por AINE. Este medicamento é contraindicado para menores de 18 anos. Categoria de risco na gravidez: D (terceiro trimestre): este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica. Informe imediatamente seu médico em caso de suspeita de gravidez. **ADVERTÊNCIAS E PRECAUÇÕES: Oxotron deve ser administrado com cautela em: Pessoas com histórico de úlcera péptica; pessoas portadoras ou com histórico de distúrbios hematológicos; pessoas portadoras ou com histórico de disfunção hepática; pessoas portadoras ou com histórico de disfunção renal; pessoas com úlcera associada ao tratamento prolongado com anti-inflamatórios não esteroides, ainda que estejam em uso de misoprostol como medida profilática; pessoas com asma brônquica de qualquer causa; pessoas com disfunção cardíaca; pessoas com história de hipersensibilidade; pessoas com colite ulcerativa; pessoas com doença de Crohn; pessoas idosas. Durante tratamento prolongado com Oxotron, exames laboratoriais, tais como urina tipo I, hemograma completo e enzimas hepáticas devem ser realizados periodicamente. Se forem observadas alterações, recomenda-se redução da dose ou interrupção do tratamento. O uso de Oxotron, bem como de outros anti-inflamatórios, pode provocar alteração do controle da pressão arterial em indivíduos hipertensos sob tratamento. Alguns efeitos indesejáveis como tontura e sonolência têm sido relatados durante o uso de Oxotron. Para segurança do paciente, solicitar cuidado ao dirigir e ao operar máquinas. A segurança do uso de loxoprofeno sódico na gestação não foi estabelecida, portanto, Oxotron somente deverá ser administrado a gestantes se os benefícios terapêuticos justificarem os riscos potenciais para o feto (particularmente no terceiro trimestre) bem como durante a lactação. Categoria de risco na gravidez: B (primeiro e segundo trimestres): Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. INTERAÇÕES MEDICAMENTOSAS: Coadministração cautelosa: Anticoagulantes cumarínicos, hipoglicemiantes sulfonilureicos, antibacteriano fluoroquinolona, metotrexate, sais de lítio, diuréticos benzotiazídicos, anti-hipertensivos. REAÇÕES ADVERSAS. Oxotron pode causar os seguintes efeitos indesejados: rash cutâneo, urticária, sonolência, edema, dor abdominal, desconforto gástrico, anorexia, náusea e vômito, diarreia e aumento das transaminases hepáticas, prurido, úlcera péptica, constipação intestinal, pirose, estomatite, urticária, dispepsia, cefaleia, anemia, leucopenia, eosinofilia, aumento da fosfatase alcalina, palpitação, fogachos, febre, sede, distensão abdominal, úlcera no intestino delgado e/ou grosso, aumento da pressão arterial, entorpecimento, tontura, trombocitopenia, hematúria, proteinúria, disúria, dor no peito e mal estar.** Outras reações adversas clinicamente significantes: choque, sintomas anafilactóides, crise asmática, Stevens-Johnson, síndrome de Lyell (necrose epidérmica tóxica), agranulocitose, anemia hemolítica, leucopenia, trombocitopenia, insuficiência renal aguda, síndrome nefrótica, nefrite intersticial, insuficiência cardíaca congestiva, pneumonia intersticial, sangramento gastrintestinal, estenose e/ou obstrução do intestino delgado e/ou grosso, perfuração gastrintestinal, disfunção hepática, icterícia, meningite asséptica e rabdomiólise. Estes casos devem ser observados cuidadosamente. A terapia com Oxotron deve ser descontinuada imediatamente e adotadas medidas de tratamento apropriadas. Foi reportado que anemia aplástica pode ocorrer com o uso de drogas anti-inflamatórias não esteroides. Em caso de eventos adversos, notifique ao Sistema de Notificações em Vigilância Sanitária – NOTIVISA, disponível em www.anvisa.gov.br/hotsite/notivisa/index.htm, ou para a Vigilância Sanitária Estadual ou Municipal. **POSOLOGIA E MODO DE USAR.** Em geral recomenda-se para o adulto a posologia de um comprimido (60 mg de Loxoprofeno sódico), três vezes ao dia, por via oral. Em casos agudos poderá ser realizada uma única administração de um a dois comprimidos (60-120 mg de Loxoprofeno sódico), por via oral, ajustando-se a dose de acordo com a idade e os sintomas. Não ultrapassar a dose diária de 180 mg, bem como evitar a administração em jejum. A segurança em pacientes pediátricos não foi estabelecida. VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573.0495. "Material técnico científico de distribuição exclusiva à classe médica".

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ACTA ORTOPÉDICA BRASILEIRA

INSTRUCTIONS TO AUTHORS

(Reviewed January 2016)

The journal *Acta Ortopédica Brasileira*, official organ of the Department of Orthopedics and Traumatology, Faculdade de Medicina da Universidade de São Paulo (DOT/FMUSP), is published bimonthly in six issues per year (Jan/Feb, Mar/Apr, May/Jun, Jul/ Aug, Sep/Oct and Nov/Dec) with Portuguese and English printed and online versions. *Acta* is distributed to orthopedists and leading educational and research institutions in Brazil. The publication follows entirely the international standard of the International Committee of Medical Journal Editors (ICMJE) – Vancouver Convention – and its uniform requirements [http://www.icmje.org/]. Submitted papers are sent for double-blind peer review evaluation to decide whether they should be published or not, suggesting improvements, asking the authors for clarification and making recommendations to the Editor-in Chief. The concepts and statements contained in the papers are the sole responsibility of the authors.

We ask authors to observe the following instructions for publication.

ARTICLES FORMAT

NUMBER OF WORDS RECOMMENDED ACCORDING TO THE PUBLICATION TYPE: The criteria specified below should be observed for each type of publication. The electronic counting of words should start at the Introduction and end at the Conclusion.

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Type of Article	Abstract	Number of words	References	Figures	Tables	Maximum number of authors allowed
Original	Structured, up to 200 words	2.500 Excluding abstract, references, tables and figures	20	10	6	6
Update / Review*	Non-structured, up to 200 words	4.000 Excluding abstract, references, tables and figures	60	3	2	2
Editorial*	No abstract	500	0	0	0	1

*These contributions shall be published at the Editors' criteria, with due replica, when applicable.

MANUSCRIPT PREPARATION: The journal *Acta Ortopédica Brasileira* receives the following types of contributions: Original Article, Update Article and Review Article. The Update and Review articles are only considered by invitation from the Editorial Board.

Manuscripts should be sent in .txt or .doc files, double-spaced, with wide margins. Measures should be expressed in the International System (*Système International*, SI), available at http://physics.nist.gov/cuu/Units and standard units, where applicable.

It is recommended that authors do not use abbreviations in the title and limit their use in the abstract and in the text.

The generic names should be used for all drugs. The drugs can be referred to by their trade name, however, the manufacturer's name, city and country or electronic address should be stated in brackets in the Materials and Methods section.

ABBREVIATIONS: The use of abbreviations should be minimized. Abbreviations should be defined at the time of its first appearance in the abstract and also in the text. Non-standard abbreviations shall not be used, unless they appear at least three times in the text.

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PRESENTATION LETTER: The cover letter accompanying the submission of the manuscript should be signed by the corresponding author and should include the following information: Title, names of all authors, text authorizing the publication of the article, stating that it has not being submitted simultaneously elsewhere and it has not been previously published (publication in another language is considered as the same article). Authors should make sure that the manuscript is entirely in accordance with the instructions.

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ACKNOWLEDGEMENTS: Authors can acknowledge financial support to the work in the form of research grants, scholarships and other, as well as professionals who do not qualify as co-authors of the article, but somehow contributed to its development.

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a) The article category (original article, review article or update article);
b) The full title in Portuguese and English with up to 80 characters. The title should be concise, but informative;
c) The full name of each author (no abbreviations) and their affiliation (hierarchical units should be presented in descending order, for example, university, college/institute and department. The names of institutions and programs should be submitted preferably in full and in the original language of the institution or in the English version when writing is not Latin (e.g. Arabic, Mandarin, Greek);
d) The place where the work was performed;
e) Name, address, telephone number and e-mail of the corresponding author.

ABSTRACT: The abstract in Portuguese and in English should be structured in cases of original articles and shall present the study's objectives clearly, methods, results and main conclusions and should not exceed 200 words (do not include any reference citations). Moreover, the abstract should include the level of evidence and the type of study, according to the classification table attached at the end of this text.

KEYWORDS: The article should include at least three and at most six descriptors in Portuguese and in English, based on the Descriptors of Health Sciences (DeCS) http://decs.bvs.br/ or Medical Subject Headings (MeSH) of the National Library of Medicine, available at http://www.nlm.nih.gov/mesh/meshhome.html

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Authors should precisely identify all drugs and chemicals used, including generic names, dosages and administration. Patients' names, initials, or hospital records should not be included. References regarding statistical procedures should be included.

RESULTS: Results should be present in logical sequence in the text, using tables and illustrations. Do not repeat in the text all the data in the tables and/or illustrations, but emphasize or summarize only the most relevant findings.

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Link the conclusions with the goals of the study, but avoid statements and conclusions that are not supported by the data, in particular the distinction between clinical and statistical relevance. Avoid making statements on economic benefits and costs, unless the manuscript includes data and appropriate economic analysis. Avoid priority claim ("this is the first study of ...") or refer to work that has not yet been completed.

CONCLUSION: The conclusion should be clear and concise, establishing a link between the conclusion and the study objectives. Avoiding conclusions not based on data from the study in question is recommended, as well as avoiding suggest that studies with larger samples are needed to confirm the results of the work in question.

ACKNOWLEDGEMENTS

When applicable, briefly acknowledge the people who have contributed intellectually or technically to the study, but whose contribution does not justify co-authorship. The author must ensure that people agree to have their names and institutions disclosed. Financial support for the research and fellowships should be acknowledged in this section (funding agency and project number).

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STATEMENT OF AUTHORS' CONTRIBUTION: The declaration of authors' contribution should be included at the end of the article, using minimum criteria for authorship, including:

- Substantial contribution in the work conception or design, or acquisition, analysis or interpretation of data to the study;
- Writing the article or critically reviewing its intellectual content;
- Approval of the final version of the manuscript to be submitted for publication;
- Agree to be responsible for all aspects of the work, to ensure that any matters regarding the completeness or accuracy of any of its parts are properly investigated and resolved;

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"Each individual author contributed individually and significantly to the development of this work. MJ (0000-0000-0000-0000)*: wrote and reviewed the and performed the surgeries; CPV (0000-0002-3904-2836)*: performed the surgeries, analyzed the data analysis and wrote the articles; JVC (0000-0003-3910-714x (0000-0000-0000-0000)*: performed statistical analysis, participated at the surgeries and reviewed the article; OMA (0000-0000-0000-0000)*: analyzed the slides and reviewed the article; MASP (0000-0000-0000-0000)*: drafted and reviewed the article and contributed to the intellectual concept of the study; ACA (0000-0001-6891-5935)*: performed the surgeries, wrote the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project. *ORCID (Open Researcher and Contributor ID)."

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Authors should make sure that all references are cited in the text. Several citations within a single set of parentheses should be separated by commas without space ([1,5,7]). Where there are 3 or more sequential citations, use a numeric range ([4-9]). Include the first six authors followed by et al.

The titles of journals should be abbreviated according to *Index Medicus*.

a) Article: Author (s). Article title. Journal title. Year; volume: initial page –final page.

Ex.: Campbell CJ. The healing of cartilage defects. Clin Orthop Relat Res. 1969;64:45-63.

b) Book: Author(s) or editor (s). Book title. Edition, if it is not the first. Translator (s), if it applies. Publication place: publisher; year.

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c) Book chapter: Chapter author (s). Chapter title. Book Editor (s) and supplementary data, likewise the previous item.

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d) Abstract: Author(s). Title, followed by [abstract]. Journal. Year; volume (supplement and its number, if it applies): page (s).

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e) Personal communications: should only be mentioned in the text, between parentheses.

f) Thesis: Author, title, level (Master, PhD, etc.), city: institution; year.

Ex.: Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis: Washington Univ.; 1995.

g) Electronic material: Author (s). Article title. Abbreviated Journal title [medium]. Publication date [access date followed by the expression "accessed on"]; volume (number):initial page-final page or [approximate number of pages]. URL followed by the expression "Available from:"

Ex.: Pavezi N, Flores D, Perez CB. Proposição de um conjunto de metadados para descrição de arquivos fotográficos considerando a Nobrade e a Sepiades. Transinf. [Internet]. 2009 [acesso em 2010 nov 8];21(3):197-205. Available from: http://periodicos.puc-campinas.edu.br/seer/index.php/transinfo/article/view/501

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Levels of Evidence for Primary Research Question[a]

(This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please visit www.cebm.net.)

	Types of study			
Level	**Therapeutic Studies Investigating the Results of Treatment**	**Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease**	**Diagnostic Studies – Investigating a Diagnostic Test**	**Economic and Decision Analyses – Developing an Economic or Decision Model**
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study[d] (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference ''gold'' standard)	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses
	Systematic review[b] of Level RCTs (and study results were homogenous[c])	Systematic review[b] of Level I studies	Systematic review[b] of Level I studies	Systematic review[b] of Level I studies
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective[f] study	Development of diagnostic criteria on consecutive patients (with universally applied reference ''gold'' standard)	Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses
	Prospective[d] comparative study[e]	Untreated controls from an RCT	Systematic review[b] of Level II studies	Systematic review[b] of Level II studies
	Systematic review[b] of Level II studies or Level I studies with inconsis tent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review[b] of Level II studies		
III	Case control study[g]	Case control study[g]	Study of non consecutive patients; without consistently applied reference ''gold'' standard	Analyses based on limited alternatives and costs; and poor estimates
	Retrospective[f] comparative study[e]		Systematic review[b] of Level III studies	Systematic review[b] of Level III studies
	Systematic review[b] of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series[h]	Case series		Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

[a] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
[b] A combination of results from two or more prior studies.
[c] Studies provided consistent results.
[d] Study was started before the first patient enrolled.
[e] Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
[f] The study was started after the first patient enrolled.
[g] Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called ''controls'' eg, successful total hip arthroplasty.
[h] Patients treated one way with no comparison group of patients treated in another way.

SUMMARY

VOLUME 25–Nº 5–2017

Original Articles

OSTEOBAN
ibandronato de sódio

PREÇO ACESSÍVEL E COMODIDADE POSOLÓGICA
na prevenção e tratamento da osteoporose[1,2,3]

1x POSOLOGIA AO MÊS[2]

PREVENÇÃO

34,4% DE REDUÇÃO do risco de **FRATURAS NÃO VERTEBRAIS.**[4]

62% DE REDUÇÃO do risco de **FRATURAS VERTEBRAIS.**[5]

MELHORA DA DENSIDADE mineral óssea em mulheres com Osteopenia e Osteoporose.[6]

Risco **5X MAIOR** da segunda fratura vertebral, após a primeira.[7]

*Estudo mostra aumento da densidade mineral óssea demonstrando prevenção da osteoporose na pós menopausa.

Referência bibliográfica: 1. Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio/2017. **2.** Bula do produto OSTEOBAN: comprimidos revestidos. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **3.** BUMBASIREVIC, M. et al. Prospective clinical study of monthly ibandronate in the treatmetn of osteoporosis and prevention of fractures in postmenopausal women: OPHEUM study. Srp Arh Celok Lek, v. 139, n. 11-12, p. 790-7694, 2011. **4.** HARRIS, S. T. et al. Ibandronate and the risk of nonvertebral and clinical fractures in women with postmenopausal osteoporosis: results of a metaanalysis of phase III studies. Curr Med Res Opin, v. 24, n. 1, p. 237-245, 2008. **5.** MILLER, P. D. et al. Efficacy of monthly oral ibandronate is sustained over 5 years: the MOBILE long-term extension study. Osteoporos Int, v. 23, n. 6, 2012. **6.** BOCK, O. et al. Impact of oral ibandronate 150 mg once monthly on bone structure and density in post-menopausal osteoporosis or osteopenia derived from in vivo µCT. Bone, v. 50, p. 317-324, 2012. **7.** STOLNICKI, B, OLIVEIRA, L.G. Para que a primeira fratura seja a última. Rev bras ortop, v. 51, n. 2, p. 121-126, 2016.

Interação Medicamentosa: Os pacientes devem esperar 60 minutos após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais. Contraindicação: OSTEOBAN é contraindicado a pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos.

Osteoban. ibandronato de sódio 150mg comprimido revestido. USO ORAL USO ADULTO. Indicações: OSTEOBAN é indicado para o tratamento da osteoporose pós-menopausa, com a finalidade de reduzir o risco de fraturas vertebrais. Em um subgrupo de pacientes de risco, com escore T < -3,0 DP no colo do fêmur, ibandronato de sódio também demonstrou reduzir o risco de fraturas não vertebrais. **Contraindicações**: **OSTEOBAN é contraindicado a pacientes com hipersensibilidade ao ibandronato de sódio ou aos demais componentes da fórmula e a pacientes com hipocalcemia não corrigida; pacientes com anormalidades do esôfago, como demora no esvaziamento esofágico, estenose ou acalasia; pacientes que não conseguem ficar em pé ou sentados durante, pelo menos, 60 minutos. Precauções e advertências: OSTEOBAN é contraindicado a pacientes com hipocalcemia não corrigida. Bisfosfonatos administrados por via oral podem causar irritação local da mucosa gastrintestinal superior. O risco de experiências adversas esofágicas graves parece ser maior para pacientes que não seguem as instruções de uso e/ou que continuaram a tomar bisfosfonatos por via oral após desenvolver sintomas sugestivos de irritação esofágica. Os pacientes devem prestar especial atenção e serem capazes de cumprir as instruções de administração. Considerando-se que anti-inflamatórios não esteróides e bisfosfonatos associam-se, ambos, à irritação gastrintestinal, recomenda-se cautela durante a administração concomitante de anti-inflamatórios não esteroides e ibandronato de sódio. Osteonecrose de mandíbula foi relatada em pacientes tratados com bisfosfonatos. A maioria dos casos em pacientes oncológicos submetidos a procedimentos dentários, mas alguns casos ocorreram em pacientes em tratamento para osteoporose pós-menopausa e outros diagnósticos. Fatores de risco conhecidos para osteonecrose de mandíbula: câncer, terapias concomitantes (ex: quimioterapia, radioterapia e corticosteroides) e distúrbios concomitantes (ex: anemia, coagulopatia, infecção e doença dentária pré-existente). A maioria dos casos foi relatada em pacientes tratados com bisfosfonatos de administração intravenosa, mas também em alguns pacientes tratados com bisfosfonatos orais.Relatos na literatura médica indicam que os bisfosfonatos podem estar associados à inflamação ocular, como uveíte e esclerite. Não foram realizados estudos sobre os efeitos de ibandronato de sódio sobre a capacidade de dirigir veículos e operar máquinas. Gestação e lactação: Categoria de risco na gravidez: B. Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista.** Não há experiência sobre o uso clínico de ibandronato de sódio em mulheres durante a gestação. OSTEOBAN não deve ser utilizado por mulheres que estejam amamentando sem orientação médica ou do cirurgião dentista. **Atenção diabéticos: contém açúcar (lactose). Interações medicamentosas:** é provável que suplementos à base de cálcio, antiácidos e alguns medicamentos orais que contenham cátions multivalentes (tais como alumínio, magnésio e ferro) interfiram na absorção de ibandronato de sódio. Os pacientes devem esperar 60 min após ingerir OSTEOBAN, antes de tomarem outros medicamentos orais. Foi demonstrada, em estudo de interação farmacocinética em mulheres na pós-menopausa, a ausência de qualquer interação potencial com tamoxifeno ou tratamentos de reposição hormonal (estrogênio). Não se observou interferência quando ibandronato de sódio foi administrado concomitantemente com melfalano / prednisolona em pacientes com mieloma múltiplo. **Interações com alimentos:** a ingestão de alimentos deve ser postergada em 60 min após a administração oral de ibandronato de sódio. **Reações adversas: reações adversas comuns (> 1/100 e ≤ 1/10): doença do refluxo gastroesofágico, diarreia, dor abdominal, dispepsia, náusea, flatulência, cefaleia, síndrome influenza–like, fadiga, artralgia, mialgia, exantema. Reação incomum (>1/1.000 e <1/100):** distúrbios gastrintestinais (gastrite, esofagite, incluindo ulcerações esofágicas ou estenose, vômitos e disfagia), distúrbios do sistema nervoso (tonturas), distúrbios musculoesqueléticos e do tecido conjuntivo (dor nas costas). **Reação rara (>1/10.000 e <1/1.000):** distúrbios gastrintestinais (duodenite), distúrbios do sistema imunológico (reações de hipersensibilidade), distúrbios da pele e do tecido subcutâneo (angioedema, edema facial e urticária). **Posologia** deve ser administrado em jejum, 60 min antes da ingestão do primeiro alimento ou bebida do dia (exceto água) e antes da administração de qualquer outro medicamento ou suplemento, inclusive cálcio. Os comprimidos devem ser deglutidos inteiros, com um copo cheio de água filtrada (180 a 240 mL). O paciente não deverá deitar-se nos 60 min seguintes após tomar o medicamento; A dose recomendada de OSTEOBAN é um comprimido de 150 mg, **uma vez por mês**. **Pacientes idosos:** não é necessário ajuste de dose. **Pacientes com insuficiência renal:** não é necessário ajuste de dose para pacientes com insuficiência renal leve a moderada e com depuração de creatinina ≥ 30 mL/min. Em pacientes com depuração de creatinina < 30 mL/min, a decisão de administrar OSTEOBAN deve ser baseada na avaliação individual da relação risco / benefício. **Pacientes com insuficiência hepática:** não há necessidade de ajuste de dose para pacientes com insuficiência hepática. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA**. MS - 1.0573.0422. **"Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à precrição e/ou dispensação de medicamentos"**. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente. MB 02-SAP. 4408302.

MOTORE
Curcuma longa 250 mg

O ANTI-INFLAMATÓRIO
COMPROVADAMENTE[3] EFICAZ E SEGURO
A LONGO PRAZO[1]

EXTRATO DE CURCUMINA COMPLEXADO
TECNOLOGIA **EXCLUSIVA**[3,4]

Exclusivo complexo curcumina-fosfatidilcolina (fitossomo):
18X mais biodisponível
em comparação à curcumina não complexada.[3]

Cientificamente comprovado
Curcumina principal fração (curcuminoide) com ação anti-inflamatória amplamente estudada.[3]

Referências Bibliográficas: 1) BELCARO, G et al: Efficacy and Safety of Meriva®, a Curcumin-phosphatidylcholine Complex,during Extended Administration in Osteoarthritis Patients. Alternative Medicine Review 15(4):337-344,2010. 2) BOSI,PL: saúde baseada em evidências. disponível em: http://disciplinas.nucleoead.com.br/pdf/Livro_SaudeBaseadaemEvidencias.pdf. Acesso em 11/2015. 3) JURENKA, S. J. Anti-inflammatory properties of Curcumin, a major constituent of Curcuma longa: a review of preclinical and clinical research. Alternative Medicine Review, v.14, n.2, p. 141-153, 2009. 4) CUOMO, J. et al. Comparative absorption of a standardized curcuminoid mixture and its lecithin formulation. J Nat Prod, v.74, p.664-669, 2011. 5) Bula do produto MOTORE: cápsulas. Responsável Técnico: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: contraindicado em caso de alergia à curcumina, açafrão *(Curcuma longa)* ou a qualquer outro componente da fórmula. É contraindicado em pacientes que estejam em tratamento com medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos. É também contraindicado em casos onde haja risco de obstrução de vias biliares ou casos de cálculos biliares, úlceras estomacais e hiperacidez do estômago.

MOTORE curcuma longa Extrato seco. **Cápsulas 250 mg. USO ORAL. USO ADULTO. Indicações**: medicamento fitoterápico destinado ao tratamento da osteoartrite e artrite reumatóide, e tem ação antiinflamatória e antioxidante. **Cuidados e advertências: a curcumina é muito bem tolerada em seu uso por via oral pela grande maioria dos pacientes, sendo raros os relatos de efeitos prejudiciais. Raramente podem ocorrer queixas como desconforto gástrico leve e movimentos intestinais mais frequentes. Precauções e advertências: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave. Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. Informe ao seu médico ou cirurgião-dentista se você está fazendo uso de algum outro medicamento. Não use medicamento sem o conhecimento do seu médico. Pode ser perigoso para a sua saúde. Gravidez e lactação:** apesar de não haver estudos conclusivos em humanos que mostrem efeito negativo na fertilidade humana, alguns estudos realizados em animais sinalizaram efeito negativo na implantação de embriões após uso injetável de altas doses de extrato etanol da curcuma. Desta maneira sugere-se evitar o uso da curcumina em pacientes com intenção de engravidar ou em gestantes. Mulheres em fase de lactação também devem evitar o uso desta medicação. Categoria de risco na gravidez C: Este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. **Interações medicamentosas: é contraindicado para uso em pacientes que estejam fazendo uso de medicações que alterem as características de coagulação como antiagregantes plaquetários, anticoagulantes, heparina de baixo peso molecular e agentes trombolíticos, pois, pode haver aumento no risco de casos de sangramento. Reações adversas: o uso da curcumina por via oral mostrou ser bem tolerada pela maioria dos pacientes. Em casos esporádicos foram relatados episódios de menor gravidade como desconforto gastrointestinal. Não há relatos de overdose ou efeito tóxico grave.** Em caso de ocorrência de reação de hipersensibilidade, a medicação deve ser imediatamente descontinuada e os sintomas avaliados pelo médico. Motore deve ser tomado apenas por via oral. Os riscos do uso por via de administração não recomendada são a não obtenção do efeito desejado e a ocorrência de reações adversas indesejadas. Não há dados de segurança relativo ao uso da curcumina em portadores de insuficiência hepática e/ou renal, não sendo recomendável o uso da medicação em pacientes nessas condições. As doses de tratamento recomendadas não devem ser excedidas. **Posologia:** Motore deve ser ingerido por via oral, com um pouco de água. A dose habitual para adultos é de 2 cápsulas a cada 12 (doze) horas, ou seja, duas tomadas diárias, totalizando 500mg de medicação a cada tomada. "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." **VENDA SOB PRESCRIÇÃO MÉDICA.** MS - 1.0573.0442. **MB 03 SAP 4437701.**

REFERÊNCIAS BIBLIOGRÁFICAS: 1) IOLASCON, G. et al. Risendronate's efficacy: from randomized clinical trials to real clinical practice. Clinical Cases in Mineral and Bone Metabolism, v. 7, n. 1, p. 19-22, 2010. 2) Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com. Acesso em: Março/2016. 3) Programa cuidados pela Vida (O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio. Desconto calculado sobre o Preço Máximo ao Consumidor). 4. BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 921, de 4 de abril de 2017. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília, DF, p. 37, 10 abril 2017.

CONTRAINDICAÇÕES: OSTEOTRAT está contraindicado em pacientes com hipersensibilidade a qualquer componente da fórmula, com hipocalcemia, durante a gravidez, lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina < 30 mL/min). INTERAÇÕES MEDICAMENTOSAS: Não foram realizados estudos formais de interação medicamentosa, entretanto, durante os estudos clínicos não foi observada qualquer interação clinicamente relevante com outros medicamentos.

OSTEOTRAT. risedronato sódico 35 mg. comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: tratamento e prevenção da osteoporose em mulheres no período pós-menopausa para reduzir o risco de fraturas vertebrais e não vertebrais. Tratamento da osteoporose em homens com alto risco de fraturas. C**ontraindicações: hipersensibilidade a qualquer componente da fórmula, hipocalcemia, gravidez e lactação e para pacientes com insuficiência renal severa ("clearance" de creatinina <30 mL/min), Precauções e advertências: Alimentos, bebidas (exceto água) e drogas contendo cátions polivalentes (tais como: cálcio, magnésio, ferro e alumínio) podem interferir na absorção dos bisfosfonatos e não devem ser administrados concomitantemente. Em mulheres mais idosas (> 80 anos), a evidência de manutenção da eficácia de risedronato sódico, é limitada. Alguns bisfosfonatos foram relacionados a esofagites e ulcerações esofágicas. Em pacientes que apresentam antecedentes de alteração esofágica que retardam o trânsito ou o esvaziamento esofágico (ex. estenososе ou acalasia), ou que são incapazes de permanecerem em posição ereta por pelo menos 30 minutos após a ingestão do comprimido, o risedronato deve ser utilizado com especial cautela. Os prescritores devem enfatizar a importância das instruções posológicas para pacientes que apresentam antecedentes de alterações esofágicas. A hipocalcemia deve ser tratada antes do início do tratamento com OSTEOTRAT. Outras alterações ósseas e do metabolismo devem ser tratadas quando iniciada a terapia com OSTEOTRAT.** Osteonecrose de mandíbula, geralmente associada com extração dentária e/ou infecção local foi relatada em pacientes com câncer em regimes de tratamento com bisfosfonatos, principalmente, na administração intravenosa. Osteonecrose de mandíbula também foi relatada em pacientes com osteoporose recebendo bisfosfonatos orais. Este medicamento contém lactose. Pacientes com problemas hereditários raros de intolerância à galactose, a deficiência da Lapp lactaseou má absorção da glucose-galactose, não devem tomar esse medicamento. Gravidez e lactação: O risco potencial para humanos é desconhecido. Risedronato sódico só deve ser utilizado durante a gravidez, se o risco benefício justificar o potencial risco para a mãe e o feto. A decisão de descontinuar a amamentação ou o produto deve considerar a importância do medicamento para mãe. Interações medicamentosas: Se considerado apropriado, OSTEOTRAT pode ser utilizado concomitantemente com a terapia de reposição hormonal. A ingestão concomitante de medicamentos contendo cátions polivalentes (ex. cálcio, magnésio, ferro e alumínio) irá interferir na absorção de OSTEOTRAT. O uso concomitante de antiácidos pode reduzir a absorção de risedronato. OSTEOTRAT não é metabolizado sistemicamente, não induz as enzimas do citocromo P450 e apresenta baixa ligação protéica. **Reações adversas: Estão listadas a seguir de acordo com a seguinte convenção: muito comum (>1/10); comum (>1/100; <1/10); incomum (>1/1000; <1/100); raro (>1/10000; <1/1000); muito raro (<1/10000). Comuns: dor de cabeça, constipação, dispepsia, náusea, dor abdominal, diarréia, dor musculoesquelética. Incomuns: gastrite, esofagite, disfagia, duodenite, úlcera esofágica Raros: glossite, estenose esofágica. Muito raramente foram observadas reações como: uveite, irite, osteonecrose de mandíbula, hipersensibilidade e reações cutâneas, incluindo angioedema, rachaduras generalizadas e reações bolhosas de pele, algumas severas. Raramente observaram-se anormalidades nos testes de função hepática. Relatos laboratoriais: foram observados em alguns pacientes discreta diminuição nos níveis de cálcio sérico e fosfato, as quais foram precoces, transitórias e assintomáticas. Posologia**: A dose recomendada nos adultos é de 1 comprimido de 35 mg uma vez por semana, por via oral. Deve ser administrado no mínimo 30 minutos antes da primeira refeição, outra medicação ou bebida (exceto água) do dia. Os comprimidos devem ser engolidos inteiros, sem deixá-los dissolvendo na boca ou mastigá-los. Os pacientes devem utilizar OSTEOTRAT enquanto estiverem na posição vertical, com um copo de água (120 mL) para auxiliar a chegada ao estômago. Os pacientes não devem deitar por 30 minutos após ingestão de OSTEOTRAT. O comprimido de Osteotrat deve ser tomado no mesmo dia de cada semana, não devem ingeridos dois comprimidos no mesmo dia. Nenhum ajuste de dose é necessário para pacientes com insuficiência renal leve a moderada. O uso do risedronato sódico é contraindicado em pacientes com insuficiência renal severa ("clearance" de creatinina menor que 30 mL/min.) "SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO." VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573.0418. MB 02_SAP 4389103. Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.

Material técnico científico de distribuição exclusiva à classe médica.

Referências Bibliográficas: 1) Bula do produto NISULID: comprimidos dispersíveis. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 2) HELSINN. The original nimesulide. 2013. Disponível em: <http://www.nimesulide.net/Default.aspx?Pagina=home&SM=home&Lingua=EN>. Acesso em: Mar. 2017. 3) Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: Maio 2017.4) BIANCHI, M; BROGGINI, M. A randomised, double-blind, clinical trial comparing the efficacy of nimesulide, celecoxib and rofecoxib in osteoarthritis of the knee. Drugs, v.63, suppl.1, p. 37-46, 2003. 5) Banco de dados da Anvisa: http://consultas.anvisa.gov.br/#/medicame.

Contraindicação: crianças menores de 12 anos. **Interação medicamentosa:** Não se aconselha usar medicamentos que provoquem irritação no estômago durante o tratamento com NISULID® (nimesulida).

NISULID. nimesulida. 100 mg comprimidos. 100 mg comprimidos dispersíveis. 100 mg / envelope granulado. 50 mg/ml gotas. 10 mg/ml suspensão oral. uso oral. 100 mg supositórios. uso retal. uso adulto e pediátrico. MS – 1.0573.0301. INDICAÇÕES: Indicado em condições clínicas que requeiram atividade anti-inflamatória, analgésica e antipirética. CONTRAINDICAÇÕES: **Hipersensibilidade à nimesulida ou a qualquer outro componente do medicamento; história de hipersensibilidade ao ácido acetilsalicílico ou a outros AINES. Pacientes com úlcera péptica em fase ativa, ulcerações recorrentes ou com hemorragia gastrintestinal; paciente com distúrbios de coagulação grave; pacientes com insuficiência cardíaca grave; pacientes com disfunção renal grave; pacientes com disfunção hepática; crianças menores de 12 anos. A nimesulida não deve ser administrada durante a gravidez ou em mulheres que estejam amamentando.** CUIDADOS E ADVERTÊNCIAS: Raramente nimesulida foi relatada estar associada com reações hepáticas sérias, incluindo casos fatais. Pacientes que apresentaram sintomas compatíveis com dano hepático durante o tratamento com nimesulida (por exemplo, anorexia, náusea, vômitos, dor abdominal, fadiga, urina escura ou icterícia) devem ser cuidadosamente monitorados. A administração concomitante com drogas hepatotóxicas conhecidas e abuso de álcool, devem ser evitados durante o tratamento com nimesulida. Pacientes que apresentaram testes de função hepática anormais devem descontinuar o tratamento e não devem reiniciar o tratamento com a nimesulida. Em raras situações, onde ulcerações ou sangramentos gastrintestinais ocorrem em pacientes tratados com nimesulida, o medicamento deve ser suspenso. Em pacientes com insuficiência renal ou cardíaca, cuidado é requerido, pois o uso de AINES pode resultar em deterioração da função renal. Pacientes idosos são particularmente sensíveis às reações adversas dos AINES, incluindo hemorragia e perfuração gastrintestinal, dano das funções renal, cardíaca e hepática. O uso prolongado de AINES em idosos não é recomendado. A nimesulida deve ser usada com atenção em pacientes com história de ulceração péptica ou inflamações intestinais. Como os AINES podem interferir na função plaquetária, eles devem ser usados com cuidado em pacientes com hemorragia intracraniana e alterações da coagulação, como por exemplo, hemofilia e predisposição a sangramento. As drogas antiinflamatórias não-esteroidais podem mascarar a febre relacionada a uma infecção bacteriana subjacente. Com relação ao uso da nimesulida em crianças, foram relatadas algumas reações graves, incluindo raros casos compatíveis com síndrome de Reye. O uso concomitante de outros anti-inflamatórios não-esteroidais durante a terapia com nimesulida não é recomendado. Como os outros anti-inflamatórios não-esteroidais, a nimesulida deve ser usada com cuidado em pacientes com insuficiência cardíaca congestiva, hipertensão, prejuízo da função renal ou depleção do volume extracelular, que são altamente suscetíveis a uma redução no fluxo sangüíneo renal. Por ser a eliminação do fármaco predominantemente renal, o produto deve ser administrado com cuidado a pacientes com prejuízo da função hepática ou renal. Em pacientes com clearance de creatinina de 30-80 ml/min, não há necessidade de ajuste de dose. Em caso de disfunção renal grave o medicamento é contra-indicado. Em pacientes com história de perturbações oculares devido a outros AINES, o tratamento deve ser suspenso e realizado exames oftalmológicos caso ocorram distúrbios visuais durante o uso da nimesulida. Pacientes com asma toleram bem a nimesulida, mas a possibilidade de precipitação de broncoespasmo não pode ser inteiramente excluída. Os riscos de uso por via de administração não-recomendada são: a não-obtenção do efeito desejado e ocorrência de reações adversas. Atenção diabéticos: contém açúcar (nas apresentações da suspensão oral (300 mg/ml), granulado (1,774 g por envelope) e gotas (300 mg/ml)). GRAVIDEZ E LACTAÇÃO: Categoria de risco de gravidez C: este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista. INTERAÇÕES MEDICAMENTOSAS: A potencial interação com glibenclamida, teofilina, varfarina, digoxina, cimetidina e uma preparação antiácida (ou seja, uma combinação de hidróxido de magnésio e alumínio) foram estudadas in vivo. Nenhuma interação clínica significante foi observada. A nimesulida pode antagonizar os efeitos dos diuréticos e em particular bloquear o aumento da atividade da renina plasmática induzida pela furosemida. O uso concomitante de furosemida e nimesulida requer cautela em pacientes renais ou cardíacos suscetíveis. A administração concomitante de nimesulida com anticoagulantes (varfarina) ou ácido acetilsalicílico pode causar efeitos aditivos (aumento do risco de complicações de sangramento). Portanto, esta combinação não é recomendada e é contra-indicada em pacientes com distúrbios de coagulação graves. Se a combinação não puder ser evitada, a atividade anticoagulante deve ser cuidadosamente monitorada. Se nimesulida for prescrita para um paciente sob terapia com lítio, os níveis de lítio devem ser monitorados cuidadosamente. Deve-se ter cuidado com pacientes que apresentem anormalidades hepáticas, particularmente se houver intenção de administrar nimesulida em combinação com outras drogas potencialmente hepatotóxicas. Não há evidência de que a nimesulida afete a glicemia em jejum ou a tolerância à glicose em pacientes diabéticos tratados com sulfoniluréias. Pode haver potencialização da ação da fenitoína. Embora não tenham sido relatados especificamente com a nimesulida, foram documentadas interações entre antiinflamatórios não-esteroidais e lítio, metotrexato, probenecida e nimesulida. Portanto, recomenda-se cuidado na administração concomitante de nimesulida com qualquer uma destas drogas, devido ao aumento do risco de hemorragias gastrintestinais. Devido ao seu efeito sobre as prostaglandinas renais, os inibidores da prostaglandina-sintetase como a nimesulida podem aumentar a nefrotoxicidade das ciclosporinas. Recomenda-se tomar NISULID após as refeições. Não se aconselha a ingestão de bebidas alcoólicas durante o tratamento. REAÇÕES ADVERSAS: **Pele e tecidos subcutâneos: prurido, rash e sudorese aumentada. Gastrintestinais: diarréia, náusea e vômito. Hepatobiliar: alterações dos parâmetros hepáticos (transaminases), geralmente transitórias e reversíveis. Casos isolados de hepatite aguda, falência hepática fulminante (algumas fatalidades foram relatadas), icterícia e colestase. Sistema nervoso: tonturas e vertigens. Sistemas visual e auditivo: raramente visão borrada. Sistema cardiovascular: hipertensão. Renais: raramente: disúria, hematúria e retenção urinária. Sistema sangüíneo e linfático: raramente: anemia e eosinofilia. Sistema imunológico: raramente hipersensibilidade. Sistema endócrino: raramente hipercalemia. Respiratórios: casos isolados de reações anafiláticas como dispnéia, asma e broncoespasmo, principalmente em pacientes com histórico de alergia ao ácido acetilsalicílico e a outros AINES. Distúrbios gerais: edema**. POSOLOGIA: USO PARA ADULTOS E CRIANÇAS ACIMA DE 12 ANOS. Comprimidos: 50 - 100mg (1/2 a 1 comprimido tomado com 1/2 copo de água) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. A administração é por via oral. Comprimidos dispersíveis: 100mg (1 comprimido) duas vezes ao dia, podendo alcançar até 200 mg duas vezes ao dia. Dissolver o comprimido em 1/2 copo de água (100 mL) ou, se preferir, o comprimido poderá ser deglutido inteiro, sem a necessidade de dissolução prévia. A administração é por via oral. Granulado: 50 a 100mg (1/2 a 1 envelope dissolvido em um pouco de água ou suco) duas vezes ao dia, podendo alcançar até 200mg duas vezes ao dia. A administração é por via oral. Supositórios: 1 supositório de 100mg duas vezes ao dia, podendo alcançar até 200mg (2 supositórios de 100mg) duas vezes ao dia. Aplicar o supositório por via retal. Gotas: administrar 1 gota (2,5mg) por kg de peso, duas vezes ao dia, diretamente na boca da criança ou se preferir diluída em um pouco de água açucarada. Lembramos que cada gota contém 2,5mg de nimesulida e cada mL de NISULID contém 50mg de nimesulida. Cada mL do produto contém 20 gotas. Suspensão: a posologia recomendada é de 5mg/kg/dia - fracionada a critério médico em duas administrações. Agitar antes de usar. Colocar a dose recomendada no copo-medida que acompanha o produto e pedir para a criança tomar pela boca (1mL da suspensão contém 10mg de nimesulida). Pacientes com insuficiência da função renal: não há necessidade de ajuste de dose em pacientes com insuficiência renal moderada. Em casos de insuficiência renal grave o medicamento é contra-indicado. Pacientes com insuficiência hepática: contra-indicado em pacientes com insuficiência hepática. VENDA SOB PRESCRIÇÃO MÉDICA. SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. Material técnico científico de distribuição exclusiva à classe médica - Documentação Científica e informações adicionais estão à disposição da classe médica, mediante solicitação. MB_ 05 SAP4094207(A)09/09.

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ROLE OF BONE GRAFTS AND BONE GRAFT SUBSTITUTES IN ISOLATED SUBTALAR JOINT ARTHRODESIS

PAPEL DO ENXERTO ÓSSEO E SUBSTITUTOS ÓSSEOS NA ARTRODESE ISOLADA DA ARTICULAÇÃO SUBTALAR

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ABSTRACT

Objectives: The purpose of this study was to compare union rates for isolated subtalar arthrodesis with and without the use of bone grafts or bone graft substitutes. Methods: We retrospectively reviewed 135 subtalar fusions with a mean follow-up of 18 ± 14 months. The standard approach was used for all surgeries. Graft materials included β-tricalcium phosphate, demineralized bone matrix, iliac crest autograft and allograft, and allograft cancellous chips. Successful subtalar fusion was determined clinically and radiographically. Results: There was an 88% (37/42) union rate without graft use and an 83% (78/93) union rate with bone graft use. Odds ratio of union for graft versus no graft was 0.703 (95% CI, 0.237-2.08). The average time to union in the graft group was 3 ± 0.73 months and 3 ± 0.86 in the non-graft group, with no statistically significant difference detected ($p = 0.56$). Conclusion: Graft use did not improve union rates for subtalar arthrodesis. ***Level of Evidence IV, Case Series.***

Keywords: Arthrodesis. Bone transplantation. Calcaneus. Subtalar joint. Transplantation, homologous.

RESUMO

Objetivos: O propósito deste estudo foi comparar as taxas de união de artrodese subtalar isolada com e sem uso de enxertos ósseos ou seus substitutos. Métodos: Revisamos retrospectivamente 135 fusões subtalares com seguimento médio de 18 ± 14 meses. A via de acesso padrão foi utilizada em todas as cirurgias. Os enxertos utilizados incluíram fosfato β-tricálcico, matriz óssea desmineralizada, autoenxerto e aloenxertos da crista ilíaca e aloenxerto de lascas de osso trabecular. A fusão subtalar bem-sucedida foi determinada clínica e radiograficamente. Resultados: Verificou-se uma taxa de união de 88% (37/42) sem uso de enxerto e de 83% (78/93) com enxerto ósseo. A análise da razão de chances (odds ratio) de união óssea para enxerto e não enxerto foi 0,703 (IC 95%, 0,237-2,08). O tempo médio de união no grupo com enxerto foi de 3 ± 0,73 meses e 3 ± 0,86 no grupo sem enxerto, sem detecção de diferença estatisticamente significante (p = 0,56). Conclusão: O uso de enxerto não melhorou as taxas de união na artrodese subtalar. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Artrodese. Transplante ósseo. Calcâneo. Articulação talocalcânea. Transplante homólogo.*

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INTRODUCTION

Subtalar joint (STJ) arthrodesis is a well-established operative procedure in the treatment of subtalar arthritis and hindfoot deformities. Indications include primary degenerative arthritis, inflammatory arthritis, post-infectious arthritis, congenital hindfoot deformities, talocalcaneal coalitions, and posterior tibial tendon dysfunction. The main goals of STJ arthrodesis are pain relief, hindfoot realignment, and functional improvement.[1-3] Traditionally, triple arthrodesis has been the operative gold standard for resistant talocalcaneal pathologies but, more recently, isolated STJ arthrodesis has seen increased advocacy. Suggested advantages of the isolated approach include simpler and shorter operations, lower risk of transverse tarsal joint nonunion or mal-union, and preservation of some hindfoot motion.[3] Nonunion remains an important complication, with incidence and role of risk factors varying in the literature. Recent reports have highlighted a decrease in overall union rates from between 96% and 100% to 84%[3,4] further strengthening the need for an understanding of risk factors that may be implicated in nonunion rates. Some possible factors have been identified including smoking, revision surgery, the presence and extent of devascularized bone, and

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previous ankle joint fusion.[4] Operative technique may represent another factor especially with regard to the degree of compression and the rigidity achieved at the fusion site.[5]
The purpose of this retrospective study was to compare the fusion rates (both clinically and radiographically) and the time to union of STJ arthrodesis with and without the use of concomitant bone grafting. We hypothesized that the use of bone grafts or bone graft substitutes would not improve union rates and time to union. We also evaluated the association of smoking and the occurrence of STJ nonunion.

MATERIALS AND METHODS

We reviewed the charts and radiographs of 133 patients who underwent 135 primary STJ arthrodesis between January 2010 and December 2013, after the approval of Research Ethics Committee of our Institution (IRB number: X160503004). There were 66 males and 67 females. Mean age was 48 (range, 18 to 74) years. Forty-one cases (feet) were smokers (26 in the graft group and 15 in the non-graft group) and 19 cases (feet) were diabetics (10 in the graft group and 9 in the non-graft group). (Table 1) Patients with concomitant or prior foot and ankle fusions, revision subtalar fusion, concomitant total ankle replacement, or distraction arthrodesis were excluded. Primary diagnoses included flat foot secondary to posterior tibial tendon dysfunction (44 feet), post-traumatic osteoarthrosis (41 feet), primary osteoarthrosis (no other specific diagnosis made) (29 feet), tarsal coalition (11 feet), inflammatory (e.g. rheumatoid) joint disease (6 feet), and neurological disorders with STJ instability (4 feet).
All patients were evaluated clinically and radiographically (AP, lateral, and subtalar views) until union was achieved or the diagnosis of nonunion was established by CT. Clinically, fusion was defined by subtalar joint stability in the absence of symptoms. Radiographically, fusion was defined as obliteration of the joint space with the presence of crossing trabeculae. CT criteria for fusion was consolidation of at least 50% of the posterior facet of the subtalar joint. All suspected cases of delayed union or nonunion were evaluated by CT.
Patients were divided into one of two operative groups – graft group or non-graft group – for comparison of the primary outcome of interest (union rate) using Fisher's exact test. Secondarily, Fisher's exact test was used in comparing the union rates in smokers and nonsmokers.

Table 1. Patient group demographics with group comparison *p* values (n = 135 feet).

	Total (n=135 feet)	Graft (n=93 feet)	Nongraft (=42 feet)	*p* value
Gender				
Male	66	48	18	**0.35**
Female	67	43	24	
Mean age (years)	48 15	47 16	51 14	**0.21**
Tobbaco use				
Smoker	41	26	15	**0.42**
Nonsmoker	94	67	27	
Diabetes				
Diabetic	19	10	9	**0.11**
Nondiabetic	116	83	33	
Mean follow-up (months)	18 14	16 13	23 14	**0.01**
Screws				
Single	16	3	13	**<0.001**
Double	119	90	29	
Parallel	11	5	6	**0.02**
Divergent	108	85	23	

Values are given as absolutely number or as mean ± SD with p values for the Fisher's exact test (significance declared when p < .05).

Logistic regression was also used to compare odds of union for graft versus non-graft and smoker versus nonsmoker. All statistical analyses were performed on SPSS 23.0 software (IBM Corporation, New York, NY, USA) with significance level set at $p < 0.05$.

Operative technique

Patients were draped and prepped (including a thigh tourniquet) in a sterile fashion. Skin incision and joint exposure were performed as described, (Figure 1) until the flexor hallucis longus (FHL) tendon was visible medially. This was followed by either drilling (for the graft group) or fish-scaling (for the nongraft group) (Figure 2) of the subchondral bone to promote healing/fusion post-fixation. Joint apposition was assessed and then followed by either bone grafting or screw fixation. Bone graft was used in 93 feet while bone graft was not used in 42 feet. Decision to graft or not to graft was based

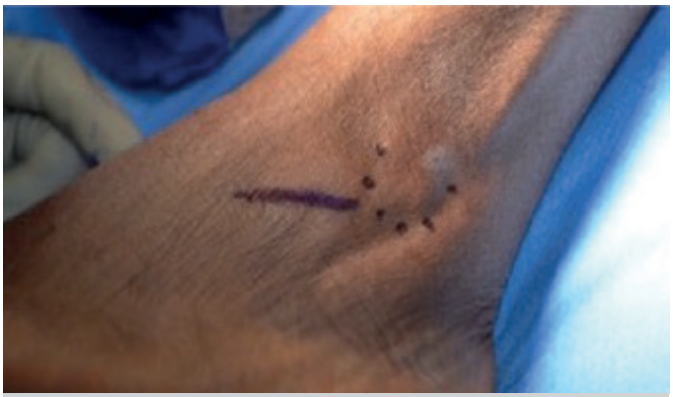

Figure 1. Clinical photograph showing the standard lateral surgical approach to the subtalar joint (sinus tarsi incision).

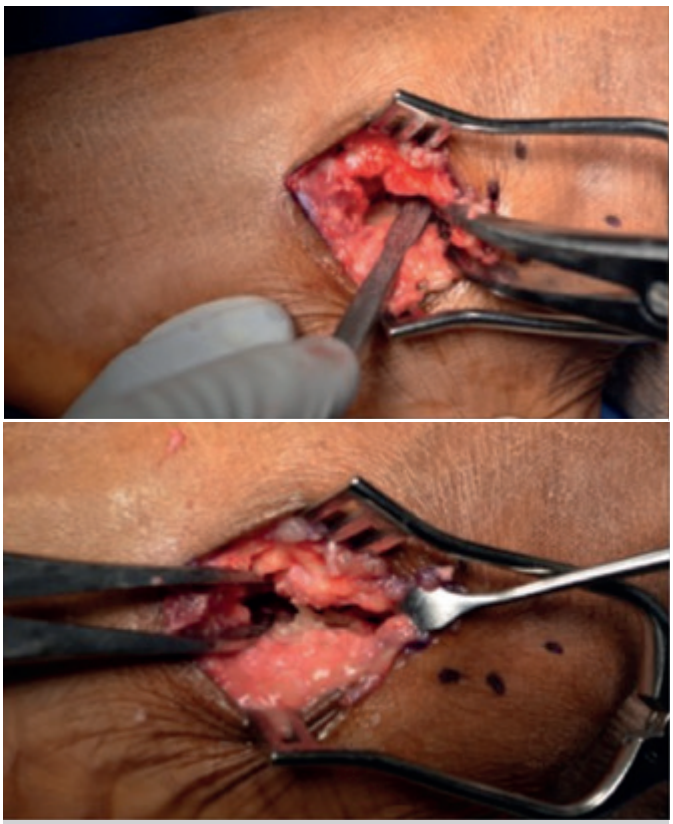

Figure 2. Intraoperative photograph showing preparation of the subtalar joint using the fish-scaling technique.

solely on surgeon preference. Graft types used included β-tricalcium phosphate (β-TCP) mixed with bone marrow aspirate (proximal tibia) (82 feet); demineralized bone matrix (DBM) mixed with bone marrow aspirate (proximal tibia) (8 feet); iliac crest autograft (2 feet); and allograft cancellous chips (1 foot).

Once bony apposition was achieved with proper hindfoot alignment, K-wires were inserted from the calcaneal tuberosity into the talar dome across the posterior facet. Positioning was confirmed fluoroscopically. With satisfactory positioning confirmed, definitive fixation was achieved using either a single 7.3mm screw (16 feet) or two 6.5mm screws (119 feet) (the gold standard for STJ arthrodesis). (Figure 3) The screws were partially threaded cancellous screws. Single-screw fixation was performed in the talocalcaneal direction. Double-screw fixation was performed in either a parallel (11 feet) or divergent fashion (108 feet) with talocalcaneal direction in 96 feet, calcaneotalar direction in 20 feet, and mixed direction (1 talocalcaneal, 1 calcaneotalar) in 3 feet.

Postoperative care

The splint was removed at 2 weeks for a wound check and stitch removal. This was followed by 6 weeks of non-weight-bearing cast use, and then removable boot cast use until clinical and radiographic confirmation of healing/fusion. Assessment of healing/fusion was performed clinically and radiographically every 6 weeks. Patients were followed for a mean of 18 ± 14 months. Poor union was determined as the presence of persistent pain and tenderness as well as poor radiographic evidence of progressive healing (i.e. lack of trabeculae across the fusion site). Patients with residual symptoms by week 16 to 20 postoperatively were evaluated by CT (Figure 4) and were then either confirmed as nonunions or explained by other pathology.

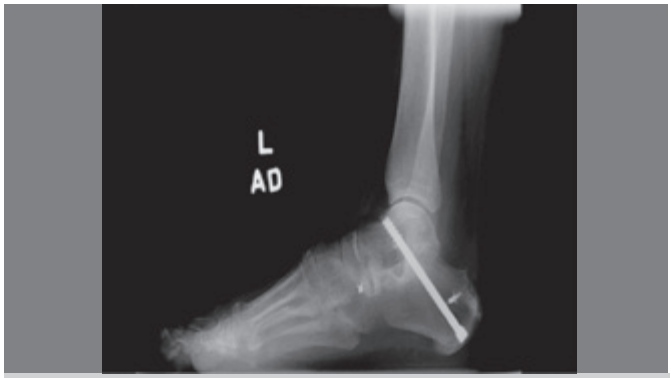

Figure 3. Postoperative plain lateral ankle radiograph showing solid union at the subtalar joint arthrodesis site using one 7.3mm lag screw.

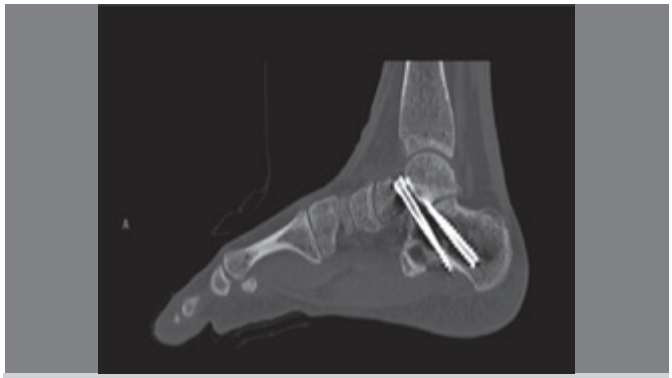

Figure 4. Postoperative sagittal CT scan cut showing nonunion at the subtalar joint arthrodesis site.

RESULTS

There was an overall union rate of 85% (115/135) and CT-confirmed nonunion rate of 15% (20/135). (Table 2) The average time to union was 3 ± 1 months. There was an 88% (37/42) union rate without graft compared to an 83% (78/93) union rate with bone graft use (TCP = 69/80; DMB = 7/8; iliac crest autograft = 1/2; allograft cancellous chips = 1/1). (Table 3) Union rate was not significantly different between the graft and nongraft groups ($p = 0.61$). Odds ratio of union for graft versus non-graft was 0.703 (95% CI, 0.237 - 2.08). The average time to union in the graft group was 3 ± 0.73 months and 3 ± 0.86 in the nongraft group with no statistically significant difference detected ($p = 0.56$).

There were 41 (feet) smokers in the study population (26 in the graft group, 15 in the non-graft group). The smoking population had a 78% (32/41) union rate compared to an 88% (83/94) union rate in nonsmokers. However, these union rates were not significantly different between smokers and nonsmokers ($p = 0.19$). (Table 2) The odds ratio of union for smokers versus nonsmokers was 0.471 (95% CI, 0.178 – 1.244). Graft smokers had a union rate of 73% (19/26) while non-graft smokers had a union rate of 87% (13/15) without being significantly different from each other ($p = 0.45$). Excluding smokers from data analysis resulted in a union rate of 88% (83/94) (85% (115/135) when included).

All of the 19 diabetic patients included in this study achieved union (10 in graft group, 9 in nongraft group). (Table 2) There were 6 patients with rheumatoid arthritis (RA) (4 in graft group, 2 in non-graft group). Only one RA patient did not achieve union and this patient was from the graft group. There was one leukemia patient on chemotherapy and this patient achieved union.

Table 2. Union rate as a function of graft status, smoking status, diabetes status, number of screws, and screw orientation (for double screws) (n = 135 feet).

	Union rate	*p* value
Grafs status		
Graft	83 (78/93)	0.35
Nongraft	88 (37/42)	
Tobbaco use		
Smoker	78 (32/41)	0.19
Nonsmoker	88 (83/94)	
Diabetes		
Diabetic	100 (1/1)	0.08
Nondiabetic	83 (96/116)	
Screws		
Single	94 (15/16)	0.46
Double	84 (100/119)	
Parallel	82 (9/11)	0.69
Divergent	84 (91/108)	

Values are given as percentage (absolutely number in parentheses) with p values for the Fisher's exact test (significance declared when $p < .05$).

Table 3. Union rate by graft type, a = β-tricalcium phosphate, b = demineralized bone matric (n = 93 feet).

Graft type	Union rate
β-TCP[a] + bone marrow aspirate (proximal tibia)	84 (69/82)
DBM[b] + bone marrow aspirate (proximal tibia)	88 (7/8)
Iliac crest autograft	50 (1/2)
Allograft cancellous chips	100 (1/1)
Total	84 (78/93)

Values are given as percentage (absolutely number in parentheses).

Complications included: 7 deep infections (3 required irrigation and debridement along with intravenous antibiotics); 1 wound dehiscence (resolved with wound care); 5 sural neuritis cases (2 required nerve block or neurectomy. Others self-resolved); 3 complex regional pain syndrome cases; 1 talar neck stress fracture (between 2 screws) (conservatively managed); 5 persistent pain cases requiring hardware removal; 2 subfibular impingements (1 required arthroscopic debridement. The other was managed non-operatively). The possible risk factors for nonunion cases are described in Table 4.

Table 4. Possible risk factors for nonunion (n = 20 feet).

Number of nonunions	Possible risk factor
6	Posttraumtic (2 were smokers in addition)
6	Smoker (only risk factor)
2	Talar AVN (1 posttraumatic, 1 RA and smoker)
6	None

Abbreviations: AVN - avascular necrosis, RA – rheumatoid arthritis.

DISCUSSION

Despite the recent trends towards minimally invasive operative techniques and the increasing use of subtalar arthroscopic fusion,[6] the open approach is still preferred for STJ arthrodesis. Many options for fixation of the arthrodesis have been described including staples,[7] dowels,[8] and lag screws.[9] However, screw fixation remains the gold standard. Regardless of the number, size or directionality (calcaneotalar or talocalcaneal) of the lag screw in fixation, union rates ranging from 86% to 100% have been reported.[4,7-9] Of note, studies with a large *n* (ranging from 95 to 184 feet) usually report union rates (85%-90%) closer to what we find in our study (85%).[4,9] On the other hand, studies finding union rates close to 100% are usually small n studies (ranging from 19 to 48 feet) (some due to significant losses in patient follow-up).[7] Although using 101 feet, Haskell et al.[9] reported a 98% union rate.

Compared to other bone graft types, autogenous bone grafts carry a lower risk of infection transmission and are more likely to incorporate at their new site since they have minimal to no immunogenicity.[10] Nonetheless, autogenous bone grafting carries significant disadvantages including donor site pain and morbidity (even with the new trapdoor harvesting technique).[11] It is also associated with prolonged operating room time (especially in nonacademic settings where the option of two surgical teams is not always available), greater blood loss, and increased postoperative pain. In addition, greater cost is incurred in cases where additional surgery is required to obtain the bone grafts.[12]

In the past decade, there has been a revolutionary change in the array of bone grafting products available[10,11] with allografts being the first alternative to autografts. Subsequently, demineralized bone matrix (DBM) was developed and became a viable substitute for allografts as an alternative to autogenous bone grafts (24-31). It has good osteoinductive properties due to release of growth factors during the demineralization process - however the sterilization process slightly decreases these osteoinductive properties.[12] When preparing DBM for implantation, it is usually mixed with bone marrow, increasing possible osteogenic factors and pluripotent cells. It can also be used as an autogenous bone graft expander.[13]

The emergence of new synthetic bone graft products has been of great interest to the orthopedic community during the last decade.[12] Synthetic bone graft materials offer an effective alternative to autografts, allografts, and demineralized bone matrix. An example of synthetic bone graft material is β-TCP, which is sterilely prepared, osteoconductive, and highly effective in filling bone void defects of the extremities.[13] When prepared with bone marrow, β-TCP provides an excellent osteoconductive structure, with osteogenic capabilities from the marrow.[12]

Scranton recommends bone grafting to avoid nonunion[14] whereas Kitaoka and Patzer[15] and Tasto[16] achieved 100% union without bone grafting, concluding that bone grafting is not necessary for obtaining joint fusion. Dahm and Kitaoka[17] also concluded that bone grafting is not essential for achieving union in STJ arthrodesis (although this was in patients following intraarticular calcaneal fracture). Joveniaux et al.[18] evaluated patients undergoing subtalar arthrodesis by grafting and found no statistically significant difference in time to union between patients with and without grafting in terms of union time. Moreover, the four revision arthrodeses in their series did not receive bone grafting during the first procedure.[18] To our knowledge, no large studies have been published to specifically compare fusion outcomes (union rates and time to union) in graft-supported STJ arthrodesis to fusion outcomes in non-grafted STJ arthrodesis.

With respect to our union rate findings for each graft type, it is difficult to make any conclusions due to scant sample sizes for each graft type except β-TCP. β-TCP, when prepared with bone marrow, provides an excellent osteoconductive structure, with osteogenic capabilities from the marrow.[12] In our study, β-TCP synthetic bone graft mixed with bone marrow aspirate was used in 82 feet with a union rate of 84% (69/82). Although, the small sample sizes for each other graft types are sub-optimal, union rates were not alarmingly different from current literature findings. Michelson and Curl[12] conducted a prospective study comparing autogenous iliac crest bone graft to DBM in 55 patients undergoing hindfoot arthrodesis, finding no significant difference in healing between the two groups of bone graft patients. Similarly, there was no significant difference in the time to healing between the iliac crest bone graft fusions and the DBM fusions. In their patient series, DBM was used in 36 hindfoot fusions with union achieved in 35 feet (97.2%).[12] Our study found a DBM union rate of 88% (7/8). As reports of DBM use in foot and ankle surgery are limited, it represents an area where more studies will be beneficial.

Easley et al.[4] reported a 92% union rate in nonsmokers versus a 73% union rate in smokers ($p < .01$). Similarly, Ishikawa et al.[19] found that smokers were 2.7 times more likely to have a nonunion when compared to non-smokers. Despite such evidence in the literature for the association of smoking with nonunion, our study fails to replicate this finding. Possible explanations may include the weakness of the effect of smoking on union rates as well as sampling bias associated with retrospective studies. Particularly, the decision to graft or not may have been influenced by intraoperative findings or implicitly by smoking status.

Our study had several limitations. To begin with, it is a retrospective study based on reviewing patients' clinical charts and radiographs, limiting information such as patient outcome scores. In the same vein, other issues associated with the lack of variable control in retrospective studies are also noted in this study. For example, we found that patients in the non-graft group were more likely to have single screw fixation when compared to patients in the graft group. Of note however, this finding reflected the inclination of a single surgeon for both single screw and non-grafted operative technique (almost all single screw cases were performed by this surgeon). Another weakness of this study is the fact that successful fusion was entirely based on clinical judgment supplemented by radiographic evidence of healing. CT scan was not obtained for every patient to confirm

union. While this would be ideal, this would expose a large number of patients to unnecessary expense and radiation. Because these patients had no pain on weight bearing and their plain radiographs confirmed union, a CT scan was not thought necessary.

CONCLUSION

The use of bone graft or bone graft substitutes in STJ arthrodesis did not result in higher fusion rates nor did they shorten the time to union when compared to STJ arthrodesis without graft use. In addition, smoking status did not negatively impact union outcome.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. CCN (0000-0001-6037-0685)* performed the data quality control and review. ALGS (0000-0002-6672-1869)* interpreted the data and performed the critical revision and final approval of the article. OE (0000-0003-4888-053X)*, IA (0000-0002-3319-1144)*, and SN (0000-0003-0538-4528)* acquired, analyzed, and interpreted the data. AS (0000-0001-58069498)* contributed to the study conception/design and drafted the manuscript. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

TRANSLATION, CULTURAL ADAPTATION AND VALIDATION OF THE FOOT FUNCTION INDEX - REVISED (FFI-R)

TRADUÇÃO, ADAPTAÇÃO CULTURAL E VALIDAÇÃO DO ÍNDICE DE FUNÇÃO DO PÉ REVISADO (FFI-R)

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ABSTRACT

Objective: The aim of this study was to translate, culturally adapt, and validate the "Foot Function Index - Revised" (FFI-R) for use in Brazilian Portuguese. Methods: The scale was translated and administered (as recommended by Guillemin, 2000) to 52 patients in the postoperative period after foot and ankle surgery. Seven days after the initial assessment, the scale was readministered by a different interviewer. The data were entered into an Excel spreadsheet and analyzed using SPSS version 23.0 software for Mac. Reproducibility was assessed using intraclass correlation analysis. Results were considered statistically significant at a type I error rate of 5%. Results: The following random-effects intraclass correlation coefficients (ICC) were obtained for each score on the FFI-R: 0.625 for pain, 0.558 for stiffness, 0.757 for difficulty, 0.718 for activity restrictions, 0.854 for personal concerns, and 0.753 for the total score. Conclusion: The FFI-R was successfully translated to Portuguese and culturally adapted for use in Brazilian patients, demonstrating satisfactory validity and reliability. ***Level of Evidence I, Testing of Previously Developed Diagnostic Criteria on Consecutive Patients (with universally applied reference "golg" standard).***

Keywords: Surveys and questionnaires. Translating. Foot diseases. Ankle injuries.

RESUMO

Objetivo: O objetivo deste estudo traduzir, fazer a adaptação cultural e a validação do "Foot Function Index - Revised" (FFI-R) para o idioma português. Métodos: A escala foi traduzida e aplicada (segundo recomendado por Guillemin, 2000) a 52 pacientes depois de cirurgia do pé e tornozelo. Sete dias depois da avaliação inicial, a escala foi novamente aplicada por outro entrevistador. Os dados foram inseridos em uma planilha do Excel e a análise estatística foi realizada no software SPSS 23.0 para Mac. A análise de correlação intraclasse foi realizada para avaliar a reprodutibilidade. Os resultados foram considerados estatisticamente significantes em erro do tipo I de até 5%. Resultados: Foram obtidos os seguintes coeficientes de correlação intraclasse (CCI) de efeitos aleatórios para cada pontuação no FFI-R: 0,625 para dor, 0,558 para rigidez, 0,757 para dificuldade, 0,718 para restrição de atividades, 0,854 para preocupações pessoais e 0,753 para o escore total. Conclusão: O FFI-R foi traduzido com sucesso para o português e adaptado culturalmente para aplicação em pacientes brasileiros, demonstrando validade e confiabilidade satisfatórias. ***Nível de Evidência I, Teste de Critérios Diagnósticos Desenvolvidos Anteriormente em Pacientes Consecutivos (com padrão de referência "ouro" aplicado).***

Descritores: *Inquéritos e questionários. Tradução. Doenças do pé. Traumatismos do tornozelo.*

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INTRODUCTION

The use of assessment scales in scientific studies is an essential requirement for the comparison of different treatments in patients with the same diagnosis.[1-9] The majority of outcome assessment scales are developed in English and directed at patients who speak this particular language. As a result, they must be translated and culturally adapted in order to be used in any other country. The statistical properties of the adapted instrument must then be evaluated based on published criteria to ensure its equivalence to the original instrument.[10,11] The aim of this study was to translate, adapt and validate the "Foot Function Index - Revised" (FFI-R) for use in Brazilian Portuguese.[12]

The FFI was developed to measure the impact of the pain, disability and activity restriction associated with foot pathology on patient functioning. It is a self-administered instrument composed of 23 items divided into three subscales.[1,13-15] The FFI has already been translated, culturally adapted and validated for use in Brazilian Portuguese.[16]

The FFI-R was developed at a later date in response to criticism of the original scale. After the unidimensionality of the FFI-R was confirmed by an analysis of its subscales, responses were coded into four categories for ease of use. The FFI is a pioneer instrument in the patient-centered measurement of foot health, and is widely used throughout the world. Its use of concrete indicators to provide

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a reliable measure of foot health introduced an important paradigm shift from subjective to objective measurements in the area of clinical foot assessments. The coding of the FFI-R into four response categories facilitated its use in the assessment of foot health.[3,12]

MATERIALS AND METHODS

The translation and cultural adaptation processes were carried out in five stages, as recommended by the literature:[10,11,17] a) stage 1 (translation): the FFI-R was first translated to Portuguese by two independent Brazilian translators, one of whom was an official translator, while the other was a technical translator with expertise in health care. Both translators were aware of the purpose of the study; b) stage 2 (synthesis): the translations were compared and discussed with the translators. When disagreements arose, changes were made as required until a consensus was reached (Portuguese version 1); c) stage 3 (back translation to English): the first Portuguese version of the scale was translated to English by two native American translators blind to the purpose of the study; d) stage 4 (expert committee review): a meeting was scheduled with all four translators to produce a "pre-final" version of the scale; e) stage 5: cultural adaptation: the pre-final version of the questionnaire was administered to 52 patients aged 18 years and older. The version was considered final when all items were judged as "not understood" by less than 10% of the sample.[1-4,12]

The inclusion criteria were late postoperative period (at least 12 months) after foot or ankle surgery at the Foot and Ankle Department of the Hospital do Servidor Público Estadual (HSPE), and absence of medication use or additional procedures for one week after the administration of the pre-final version of the questionnaire to ensure reproducibility. The presence of cognitive impairments which could interfere with the administration of the questionnaire was the only exclusion criterion.

The sociocultural characteristics of the 52 patients in the late postoperative period after foot and ankle surgery who participated in the reproducibility and validation studies of the Portuguese version of the FFI-R were as follows: 39 were female (75%), and 13 were male (25%); mean age was 56 years (range: 39 to 81 years); mean length of postoperative period was 4 years (range: 1 to 11 years); 22 had completed secondary education, 29 had a university degree, and one had gone to graduate school. Study approved in the Brazilian Platform CAAE: 49066915.9.0000.5463 under Opinion constituted 1,283,807.

Reproducibility and validity of the portuguese version of the FFI-R

The reproducibility of the Portuguese version of the FFI-R was evaluated in a sample of 52 patients in the late postoperative period after foot or ankle surgery. The scale was administered by a previously trained interviewer (interviewer 1). After a seven day period, a new assessment was conducted by interviewer 2.

Data were entered into an Excel® spreadsheet and analyzed using SPSS version 23.0 for MAC. The mean and standard deviation of each item in the Brazilian version of the FFI-R were calculated. The relationship between the assessments was evaluated by linear correlation analysis followed by paired comparisons of scores on the first and second evaluations. This procedure was performed using non-parametric methods due to the skewed distribution of the data. Lastly, reproducibility was assessed using intraclass correlation (ICC) analysis. Results were considered statistically significant at a type I error rate of 5%.

RESULTS

When the pre-final version of the questionnaire was administered to the validation sample in the cultural adaptation stage, no item reached the 10% comprehension threshold, and as such, the instrument was deemed culturally appropriate. The final version of the FFI-R in Portuguese is presented in the Appendix 1. The mean time of questionnaire administration was 20 minutes, and the interval between the two assessments was seven days.

The mean ± SD of pain scores on the first and second assessment were 44.46%±21.36 and 39.21%±18.36, respectively. The Spearman correlation between these values was 0.674, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects intraclass correlation coefficient (ICC) corresponding to the test-retest reliability of this particular score was 0.625 [95%CI 0.428 to 0.766], $p<0.001$. (Table 1)

The mean ± SD of stiffness scores on the first and second assessment were 39.00%±20.54 and 38.96%±17.40, respectively. The Spearman correlation between these values was 0.513, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects ICC of the stiffness score was 0.558 [95%CI 0.340 to 0.719], $p<0.001$.

The mean ± SD of difficulty scores on the first and second assessment were 44.47%±28.33 and 39.81%±24.01, respectively. The Spearman correlation between these values was 0.754, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects ICC of the FFI-R difficulty score was 0.745 [95%CI 0.595 to 0.845], $p<0.001$.

The mean ± SD of activity limitation scores on the first and second assessment were 41.35%±23.29 and 40.97%±21.05, respectively. The Spearman correlation between these values was 0.756, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects ICC of the activity limitation score was 0.718 [95%CI 0.556 to 0.827], $p<0.001$.

The mean ± SD of social activity scores on the first and second assessment were 36.44%±23.64 and 39.95%±19.57, respectively. The Spearman correlation between these values was 0.691, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects ICC of the social functioning score was 0.854 [95%CI 0.700 to 0.913], $p<0.001$.

The mean ± SD of total scores on the first and second assessment were 41.01%±4.23 and 39.01%±0.09, respectively. The Spearman correlation between these values was 0.760, significant at $p<0.001$. The two scores did not significantly differ according to Wilcoxon's paired t-test, $p=0.06$. The random-effects ICC of total scores on the FFI-R was 0.793 [95%CI 0.667 to 0.876], $p<0.001$.

Table 1. Random-effects intraclass correlation coefficient (ICC) for pain scores.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.625	.428	.766	4,338	51	52	.000

DISCUSSION

When assessing the outcome of orthopedic treatments, there is often significant concern about the impact of the intervention on the patient's quality of life, emotional well-being, and performance in daily activities.[18] Two main challenges are often faced in the assessment process: one concerns the quantification of subjective information and the selection of questions for assessment instruments, while the other involves the administration of these questionnaires in different countries to allow for cross-cultural comparisons.[19,20] These instruments are usually developed in English, and must therefore be translated and analyzed for their statistical properties prior to being used in any other cultural context.[1,2,10,11]

In the present study, no comprehension issues were encountered, since all items in the questionnaire refer to patients' daily activities. In the cultural adaptation stage, no item reached the 10% comprehension threshold, and as such, the pre-final version of the FFI-R was deemed culturally appropriate.

The reproducibility of the Portuguese version of the FFI-R was evaluated in a sample of 52 patients in the late postoperative period after foot or ankle surgery. The scale was first administered by a previously trained researcher (assessment 1), then readministered by another interviewer (assessment 2). Scores on assessments 1 and 2 did not significantly differ from one another and were significantly correlated, which speaks to the reliability of the instrument. The Portuguese version of the FFI-R was also shown to have strong internal consistency, as evidenced by intraclass correlation analysis. (Tables 1 to 6)

Table 2. Random-effects intraclass correlation coefficient (ICC) for stiffness scores.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.558	.340	.719	3,522	51	52	.000

Table 3. Random-effects intraclass correlation coefficient (ICC) for difficulty scores.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.745	.595	.845	6,833	51	52	.000

Table 4. Random-effects intraclass correlation coefficient (ICC) for activity limitation scores.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.718	.556	.827	6,083	51	52	.000

Table 5. Random-effects intraclass correlation coefficient (ICC) for social functioning scores.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.854	.760	.913	12,715	51	52	.000

Table 6. Random-effects intraclass correlation coefficient (ICC) for total scores on the FFI-R.

	Intraclass correlation	95% Confidence interval		F Test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	.793	.667	.876	8,678	51	52	.000

CONCLUSION

The FFI-R was successfully translated and culturally adapted for use in Brazilian patients, demonstrating satisfactory validity and reliability.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. KCS (0000-0003-1534-9654)* performed the translation into Portuguese and written the manuscript. MVPF (0000-0002-2320-9769)* Carried out a bibliographic review. PRO (0000-0002-1991-1571)* e PYLW (0000-001-5204-7095)* Applied the score as evaluators 1 and 2 respectively. *ORCID (Open Researcher and Contributor ID).

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Appendix 1. Instrumento 1 - IFP-Índice Funcional do Pé formato longo Versão 3.

RG do indivíduo: [___]___]___]____] Indíce Funcional do Pé Revisado (IFP-R) Data: [__]__] / [__]__] / [__]__]__]

DOR

Por favor, leia antes de responder.

- Por favor, circule o número que indica qual a intensidade da sua dor no pé em cada situação a seguir na última semana
- Por exemplo, quando perguntado a intensidade da sua dor no pé no seu pior momento, se você não sentiu "nenhuma dor" circule o número 1 e se você sentiu "dor intensa" circule o número 4
- Se, para alguns itens, a questão não é pertinente circule o número 5
- Por favor, forneça uma resposta para cada item

1. Na última semana qual a intensidade da sua dor no pé:

	Sem dor	Dor leve	Dor moderada	Dor intensa	
1. Antes de se levantar da cama pela manhã?	1	2	3	4	
2. Quando ficou em pé descalço pela primeira vez?	1	2	3	4	
3. Quando andou descalço pela primeira vez?	1	2	3	4	
4. Quando ficou em pé com sapatos?	1	2	3	4	
5. Quando andou com o sapatos?	1	2	3	4	
6. Quando ficou em pé com as palmilhas feitas sob medida?	1	2	3	4	5 – não uso palmilhas
7. Quando andou com as palmilhas feitas sob medida?	1	2	3	4	5 – não uso palmilhas
8. No final de um dia típico?	1	2	3	4	
9. Quando você sentiu cãimbras nos pés?	1	2	3	4	
10. Antes de você se deitar à noite?	1	2	3	4	
11. No pior momento	1	2	3	4	

RIGIDEZ

Por favor, leia antes de responder.

- Por favor, circule o número que indica qual a intensidade da sua rigidez no pé em cada situação na última semana
- Por exemplo, quando perguntado a intensidade da sua rigidez no pé no seu pior momento, se você não sentiu "nenhuma rigidez" circule o número 1 e se você sentiu "rigidez intensa" circule o número 4
- Se, para alguns itens, a questão não é pertinente circule o número 5
- Por favor, forneça uma resposta para cada item

1. Na última semana qual a intensidade da rigidez no pé:

	Sem dor	Dor leve	Dor moderada	Dor intensa	
12. Antes de se levantar da cama pela manhã?	1	2	3	4	
13. Quando ficou em pé descalço?	1	2	3	4	
14. Quando andou descalço?	1	2	3	4	
15. Quando ficou em pé com sapatos?	1	2	3	4	
16. Quando andou com sapatos?	1	2	3	4	
17. Quando andou com as palmilhas feitas sob medida ?	1	2	3	4	5 – não uso palmilhas
18. Antes de você se deitar à noite?	1	2	3	4	
19. No pior momento	1	2	3	4	

DIFICULDADE

Por favor, leia antes de responder.

- Por favor, circule o número que indica qual a intensidade de dificuldade que você sentiu para realizar cada atividade devido a seus problemas no pé na última semana
- Por exemplo, quando perguntado qual a dificuldade que seus problemas no pé causou quando você andou pela casa, se você não sentiu "nenhuma dificuldade" circule o número 1 e se você sentiu "dificuldade intensa" circule o número 4
- Se, em alguns itens, a questão não se aplica circule o número 5
- Por favor, forneça uma resposta para cada item

1. Na última semana qual a intensidade de dificuldade que seus problemas no pé lhe causaram:

	Sem dificuldade	Dificuldade leve	dificuldade moderada	Dificuldade intensa
20. Andando pela casa?	1	2	3	4
21. Andando fora de casa em terreno irregular?	1	2	3	4
22. Andando quatro ou mais quarteirões?	1	2	3	4
23. Subindo escadas?	1	2	3	4
24. Descendo escadas?	1	2	3	4
25. Ficando na ponta dos pés?	1	2	3	4
26. Ficando em pé normalmente?	1	2	3	4
27. Quando você carregou ou levantou objetos com mais de 2,5kg	1	2	3	4
28. Levantando de uma cadeira	1	2	3	4
29. Andando rápido	1	2	3	4
30.Correndo	1	2	3	4

Appendix 1. Instrumento 1 - IFP-Índice Funcional do Pé formato longo Versão 3.

	Sem dificuldade	Dificuldade leve	dificuldade moderada	Dificuldade intensa	
31. Descendo uma ladeira a pé	1	2	3	4	
32. Andando em ritmo constante	1	2	3	4	
33. Andando sua distância habitual?	1	2	3	4	
34. Mantendo-se em equilíbrio?	1	2	3	4	
35. Fazendo a higiene do seu pé?	1	2	3	4	
36. Andando com auxiliares de marcha?	1	2	3	4	
37. Devido aos riscos na sua casa?	1	2	3	4	
38. Dirigindo veículo que requer seu pé para manobras	1	2	3	4	
39. Realizando suas atividades de vida diária?	1	2	3	4	

LIMITAÇÃO DE ATIVIDADES

Por favor, leia antes de responder.

- Por favor, circule o número que indica com que frequência você realizou cada uma dessas atividades na última semana devido aos dos seus pés
- Por exemplo, quando perguntado qual a frequência que você usou bengala dentro de casa devido a seus problemas nos pés , se você "nunca" usou circule o número 1 e se você "usou o tempo todo" circule o número 4
- Se, para alguns itens, a questão não é pertinente circule o número 5
- Por favor, forneça uma resposta para cada item

1. Na última semana quanto tempo você:

	Nunca	Algumas vezes	A maior parte do tempo	O tempo todo	
40. Usa uma bengala, muletas ou andador dentro de casa devido aos problemas no pé?	1	2	3	4	5=nãousobengalas,etc
41. Usa uma bengala, muletas ou andador fora de casa devido aos problemas no pé?	1	2	3	4	5=não uso muletas,etc
42. Fica dentro de casa a maior parte do dia devido aos problemas no pé?	1	2	3	4	
43. Fica na cama a maior parte do dia devido aos problemas no pé?	1	2	3	4	
44. Toma cuidado extra quando anda no meio de muita gente por medo de lesão no pé?	1	2	3	4	5=não ando no meio de muita gente
45. Limita sua atividades fora de casa devido aos problemas no pé?	1	2	3	4	5=não faço atividades fora de casa
46. Limita sua atividadesde laser/esportes devido aos problemas no pé?	1	2	3	4	5=não pratico esportes
47. Escolhe não usar transporte público devido aos problemas no pé?	1	2	3	4	5=não uso tranp. público
48. Escolhe não dirigir devido aos problemas no pé?	1	2	3	4	5=não dirijo

QUESTÕES SOCIAIS

Por favor, leia antes de responder.

- Por favor, circule o número que indica qual a frequência você sentiu o seguinte na última semana devido a seus pés
- Por exemplo, quando perguntado com que frequência você sentiu medo de cair por causa de seus problemas no pé , se você "nunca" sentiu medo circule o número 1 e se você sentiu "o tempo todo" circule o número 4
- Se, para alguns itens, a questão não é pertinente circule o número 5
- Por favor, forneça uma resposta para cada item

1. Na última semana quanto tempo você sentiu:

	Nunca	Poucas vezes	Algumas vezes	A maior parte do tempo	
49. Medo de cair?	1	2	3	4	
50. Vergonha de mancar?	1	2	3	4	5=não manca
51. Dificuldade de encontrar calçados da moda?	1	2	3	4	5=não usa sapatos da moda
52. Dificuldade de encontrar sapatos sociais?	1	2	3	4	
53. Vergonha por causa do calçado?	1	2	3	4	
54. Depressão por problemas nos pés?	1	2	3	4	
55. Dificuldade de encontrar um calçado adequado?	1	2	3	4	
56. Terrível pelos problemas nos pés?	1	2	3	4	

Appendix 1. Instrumento 1 - IFP-Índice Funcional do Pé formato longo Versão 3.

	Nunca	Poucas vezes	Algumas vezes	A maior parte do tempo
57. Limitação das atividades sociais devido aos problemas no pé?	1	2	3	4
58. Irritação constante por você ter que administrar a dor no pé?	1	2	3	4
59. Dificuldade de participar de atividades sociais devido ao calçado?	1	2	3	4
60. Piora para realizar as atividades diárias?	1	2	3	4
61. Sono ruim devido a dor no pé?	1	2	3	4
62. Peso de precisar tomar as medicações para controlar a dor no pé ?	1	2	3	4
63.Dificuldade de encontrar calçados confortáveis?	1	2	3	4
64. Dificuldade de encontrar emprego devido aos problemas no pé?	1	2	3	4
65. Preocupação com a aparência dos seus pés?	1	2	3	4
66. Preocupação com a limitação do trabalho doméstico?	1	2	3	4
67. Preocupação com a possibilidade de amputação do pé, perna ou dedos do pé?	1	2	3	4

COMENTÁRIOS PESSOAIS

Por favor comente sobre:
1. As orientações foram claras?
2. Alguma das questões foi difícil de entender?
3. Alguma das questões não foi clara? Se sim, quais e por que?
4. Alguma das questões que lhe incomodou? Se sim, quais e por que?
5. Há alguma questão a respeito do seus pés que não foi perguntada ou você acrescentaria ao questionário? Se sim, quais questões?
6. Você teve algum problema com esse questionário que você gostaria de mencionar? Se sim, quais problemas?

Obrigada por participar desse estudo:

Pontuação de dor_____
Pontuação de rigidez_____
Pontuação de dificuldade_____
Pontuação de atividades_____
Pontuação social_____
Pontuação acumulada_____

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ORIGINAL ARTICLE

FACTORS ASSOCIATED WITH COMPLEX REGIONAL PAIN SYNDROME IN SURGICALLY TREATED DISTAL RADIUS FRACTURE

FATORES ASSOCIADOS À SÍNDROME DE DOR REGIONAL COMPLEXA EM FRATURA DO DISTAL DO RÁDIO TRATADA CIRURGICAMENTE

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ABSTRACT

Objective: The aim of this study was to identify factors associated with developing complex regional pain syndrome (CRPS) after surgical treatment for distal radius fracture (DRF). Methods: This case-control study analyzed patients seen from January 2014 to January 2016. Results: In our sample of 249 patients, 4% developed CRPS. Associated factors were economic compensation via work disability (odds ratio [OR] 14.3), age (OR 9.38), associated fracture (OR 12.94), and level of impact (OR 6.46), as well as psychiatric history (OR 7.21). Conclusions: Economically-productive aged patients with a history of high-impact trauma and patients with a history of psychiatric disorders have greater risk of developing CRPS after DRF. ***Level of Evidence III, Case-Control Study.***

Keywords: Radius fractures. Surgical procedures, operative. Reflex sympathetic dystrophy. Complex regional pain syndrome. Insurance beneficiary.

RESUMO

Objetivo: Este estudo tem como objetivo identificar fatores de risco associados ao desenvolvimento de síndrome de dor regional complexa (CRPS) após o tratamento cirúrgico da fratura distal do rádio (DRF). Métodos: Este estudo de caso/controle analisou pacientes atendidos de janeiro de 2014 a janeiro de 2016. Resultados: Em nossa amostra de 249 pacientes, 4% desenvolveram CRPS. Os fatores associados foram compensação econômica (razão de chances [RC] 14,3), idade (RC 9,38), fratura associada (RC 12,94) e nível de impacto (RC 6,46), bem como história psiquiátrica (RC 7,21). Conclusões: Os pacientes com idade produtiva e história de trauma de alto impacto e os com história de transtornos psiquiátrico têm maior risco de desenvolver CRPS depois de DRF. ***Nível de Evidência III, Estudo de Caso Controle.***

Descritores: *Fraturas do rádio. Procedimentos cirúrgicos operatórios. Distrofia simpática reflexa. Síndrome da dor regional complexa. Benefícios do seguro.*

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INTRODUCTION

The aim of this study was to identify risk factors associated with the development of complex regional pain syndrome (CRPS) in patients with distal radius fractures (DRF) treated surgically. DRF have been identified in humans since we have walked upright, but treatment from ancient times to the mid-twentieth century was similar and had a high rate of complications. Surgical management was introduced during the 1970s, and at the beginning of the 21st century various treatment options were offered.[1] DRF is the most common human fracture (1/6 of all fractures) regardless of age.[2] In the adult population, persons >60 years of age, postmenopausal women, and urban residents have a higher risk for DRF. Young adults are at lower risk for DRF, but this group is occupationally active and sequelae in this age group have more significant consequences.[2,3]

CRPS is a complication that can present as multiple injuries characterized by chronic, persistent pain (severe and debilitating) in the absence of cell damage. It is characterized by autonomic pain and sensory (allodynia, hyperesthesia), motor, trophic (osteopenia), and vasomotor changes (hyperemia and hyperthermia) that culminate in dysfunction of the extremity.[4] Patients with DRF develop CRPS in 1–37% of cases, with a direct impact on quality of life, psychosocial wellbeing, and decrease in work capacity.[5,6] CRPS varies in appearance and may occur immediately or weeks after trauma or surgical treatment;[4] this syndrome is classified into type I (without evidence of nerve damage) and type II (with evidence of nerve injury).[7,8]
Risk factors for developing CRPS in the upper extremities have been studied extensively and associated with various surgical procedures such as dermofasciotomy and carpal tunnel release. DRF

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is associated in 30% of cases of CRPS in the upper extremities.[5,9] Few studies mention risk factors for CRPS in patients who present DRF with surgical management.[6] The objective of this study is to identify the demographic risk factors of the injury for developing CRPS in patients who received surgical treatment for DRF.

MATERIALS AND METHODS

A case-control study with non-probabilistic consecutive sampling was carried out in patients seen from January 2014 to January 2016 in order to identify factors associated with the development of CRPS after surgical treatment for DRF. This study was approved by the institutional review board (registration number R-2016-3401-24) and was carried out in accordance with the Declaration of Helsinki (1995). The results obtained are strictly confidential and were strictly for academic use. Informed consent was not required because the study collected secondary data (from medical records) and the natural history of the disease was not altered.

We included patients over 18 years of age with open or closed DRF who received surgical treatment and had a complete medical record and X-ray available in the digital system. We excluded patients who received surgical treatment in the emergency department because they did not have a complete medical record. The included patients developed pain after standard surgical treatment that was not alleviated by standard analgesia and were assessed by anesthesiologists specializing in pain management who diagnosed CRPS according to the Budapest criteria.[8,10] The controls were patients who did not develop pain after surgical treatment, or who had a good response to standard analgesia.

A total of 249 patients were included in the study. All patients were treated surgically by experts in trauma and orthopedics with over 5 years of experience. After the surgery, follow-up was provided until consolidation. All cases were tracked via an electronic outpatient system until discharge or diagnosis with CRPS by the pain specialist. Risk factors related to CRPS are multifactorial and based on prior included studies,[6,11,12] age >60 years, sex, exposed fracture, high-impact injuries (carpal luxation fracture, fracture of long bones, associated fracture of the humerus, femur, scapula, or craniofacial bones, loss of consciousness, motor vehicle injuries), low impact injuries (simple stroke, fall from own height), exposed fracture, high number of manipulations, presence of comorbidities, psychiatric history, type of fracture according to Fernandez classification, AO type of fracture, type of treatment, and number of manipulations. All surgeries were performed by orthopedic surgeons with >6 years surgical experience with DRF. Patients who were managed with closed reduction and external fixation (CREF) in addition to mixed osteosynthesis (MO) were kept immobilized until X-rays showed consolidation, after which the fixator was removed and the patient was referred to physical rehabilitation. In patients with open reduction and internal fixation (ORIF), antebrachial splint immobilization was maintained and subsequently removed systematically at 7–14 days to initiate active mobilization and rehabilitation exercises. Flexion and extension exercises of the elbow and fingers were indicated from the immediate postoperative period. After consolidation was corroborated via X-ray, all patients were sent to the physical and rehabilitation medicine department where they were given a physiotherapy form and instructions on how to perform the exercises at home.

RESULTS

A 4% incidence of CRPS (10 cases) was identified. Demographic characteristics of the population and results after calculating the odds ratio (OR) of the variables studied are summarized in Table 1. Table 2 summarizes the times related to each type of treatment.

DISCUSSION

Reports on complications of DRF and its definitive surgical management describe a 3–25% incidence of CRPS.[13] In this study we found an incidence of 4%, which is within the internationally reported values.

We found that patients with surgically-managed DRF associated with development of CRPS were direct beneficiaries (received economic compensation for work disability), had fractures associated with another bone, were <60 years of age, had psychiatric history, and had injuries related to high-impact injuries. Multiple studies have reported that females have up to twice the risk of developing CRPS,[5,6,11,14] but we found no difference between sexes in this study.

Table 1. Demographic characteristics and OR for dichotomous variables.

Variable	n	Cases CRPS (+) n:10	Controls CRPS (–) n: 239	OR	CI	P
Female	169	5	164	2.1867	0.614-7.781	0.227
Male	80	5	75			
Direct economic beneficiary	101	9	92	14.38	1.79-115.38	0.0121
Without economic	148	1	147			
<60 years of age	126	9	117	9.3846	1.170-75.233	0.035
>60 years of age	123	1	122			
Exposed fx	2	0	2	4.5238	0.204-100.287	0.339
Closed fx	247	0	247			
Associated fx	107	9	98	12.949	1.614-103.861	0.0159
Non associated fx	142	1	141			
High energy	51	6	45	6.466	1.751-23.872	0.005
Low energy	198	4	194			
Tx CREF	154	6	148	0.9223	0.253-3.356	0.9023
Tx ORIF	67	2	65	0.669	0.138-3.234	0.6173
Tx MO	28	2	26	2.048	0.412-10.165	0.3805
≥ 2 manipulations	59	3	56	1.4005	0.350-5.596	0.6337
One manipulation	190	7	183			
Diabetes mellitus	55	0	55	0.1583	0.009-2.744	0.2054
No Diabetes mellitus	194	10	184			
Arterial hypertension	82	0	82	0.0909	0.005-1.570	0.991
No arterial hypertension	167	10	157			
Psychiatric history	10	2	8	7.2188	1.315-39.606	0.0229
No psychiatric history	239	8	231			

OR, odds ratio; CI, confidence interval; Tx, treatment; fx, fracture; CREF, closed reduction external fixation; ORIF, open reduction internal fixation; MO, mixed osteosynthesis; RA, rheumatoid arthritis; CRI, chronic renal insufficiency.

Table 2. Surgical treatment

CREF (n=154)		
Variable	**Mean**	**SD**
Ischemia time (minutes)	3.34	15.85
Surgical time (minutes)	33.2	17.67
Immobilization time (days)	53.8	11.55
ORIF (n=67)		
Variable	**Mean**	**SD**
Ischemia time (minutes)	56.93	21.06
Surgical time (minutes)	62.6	24.33
Immobilization time (days)	32.3	23.79
MO (n=28)		
Variable	**Mean**	**SD**
Ischemia time (minutes)	71.54	32.89
Surgical time (minutes)	79.54	41.59
Immobilization time (days)	48.43	12.73

CREF, closed reduction and external fixation; ORIF, open reduction and internal fixation; MO, mixed osteosynthesis; SD, standard deviation.

Another study reported an association between advanced age and CRPS,[6] with a mean age of 56 years, but in our study patients <60 years of age demonstrated a higher risk of developing CRPS.

Another study describing injuries associated with DRF focused on damage to the carpal bones, triangular fibrocartilaginous complex, and distal ulna; while this same study reported development of distal ulnar radial instability, carpal collapse, and residual pain, it did not describe CRPS.[15] Additionally, 17.2% of a series of 721 patients presented an associated fracture with short-term follow-up but without reports of subacute or chronic complications such as CRPS.[16] This differs from our results, where associated fractures were very common (frequency of 43%). Studies describing DRF and multiple fractures have not analyzed the relationship with CRPS.[6,7,11,17,18] A study by Rozen et al.[19] reviewing exposed DRFs did not mention higher risk for CRPS; we agree with this study because our patients with exposed fractures were not more likely to develop CRPS.

High-impact injuries have already been considered significant, with twice the risk for developing CRPS.[5,6] We found similar results, although the probability of developing CRPS in our study was five times greater. As for type of treatment, some sources report that management with CREF increases the risk of developing CRPS vs. MO with volar plate.[20–22] We did not find any difference among the three types of surgical treatment (CREF, ORIF, and MO with volar plate) in terms of developing CRPS. Longer immobilization time or prolonged times of bone consolidation have been reported to be associated with CRPS (immobilization typically lasts 6 to 8 weeks).[9] Our patients who were immobilized >8 weeks did not demonstrate increased probability of developing CRPS.

History of psychiatric disease such as anxiety or depression has been associated with image simulation or with patients who are hyper-reactive to injuries and have a low pain threshold.[23] Jellad et al.[11] evaluated 90 patients with a history of anxiety or depression who received conservative management of DRF and did not find higher risk of CRPS. In our study, a positive association was found with a history of psychiatric disease, with a six-fold increase for development of CRPS. This study analyzed a number of comorbidities such as chronic kidney disease, osteoporosis, history of cancer, asthma, pulmonary diseases, rheumatoid arthritis, hypothyroidism, Parkinson's disease and Herpes Zoster infection. Nevertheless, none of these comorbidities indicated a significant relation to developing CRPS.

One limitation of this study is the follow-up time for the patients managed surgically. After radiographic confirmation of consolidation, the patients were discharged and referred to a rehabilitation center along with follow-up by the family physician, and CRPS may consequently be clinically underdiagnosed. Another limitation of the study is the sample size and retrospective design.

CONCLUSION

Patients who may have a secondary benefit from prolonged disability due to DRF have a higher risk of developing CRPS. In addition, patients <60 years of age with associated fractures are closely related with high-impact fractures, generally from automobile accidents, falls from height, and sports, and have an elevated risk of developing CRPS. Patients with a psychiatric history have a greater risk of developing CRPS.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. JOR (0000-0003-1115-7532)* and JMPA (0000-0003-4188-9208)* conceived and designed the study, acquired, analyzed, and interpreted the data, wrote the article, and approved the final version of manuscript. IBS (0000-0003-2592-4210)* and RTG (0000-0001-9098-2199)* approved the final version of the manuscript. FEC (0000-0002-49712573)* and JAZH (0000-0002-8687-9823)* critically reviewed the intellectual content of the study. *ORCID (Open Researcher and Contributor ID).

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INFLUENCE OF AGE ON PARAMETERS FOR FEMOROACETABULAR IMPINGEMENT AND HIP DYSPLASIA IN X-RAYS

INFLUÊNCIA DA IDADE SOBRE OS PARÂMETROS PARA IMPACTO FEMOROACETABULAR E DIPLASIA DO QUADRIL EM RADIOGRAFIAS

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ABSTRACT

Objective: While several radiographic parameters have been established to describe the geometry and pathology of the hip, their reference values and clinical significance remain a matter of dispute. The present study tests the hypothesis that age has a relevant impact on radiographic hip parameters. Method: Pelvic antero-posterior views were measured for CE angle, Sharp's angle, acetabular depth-to-width ratio, femoral head extrusion index, roof obliquity, caput-collum-diaphyseal (CCD) angle, and Murray's femoral head ratio, and the values obtained were correlated with age. Results: Significant weak and moderate linear correlations (all Ps<0.001) were observed between age and CE angle (ρ=0.31), Sharp's angle (ρ=-0.38), extrusion index (ρ=-0.22), CCD angle (ρ=-0.15), depth-to-width ratio (ρ=-0.38), and roof obliquity (ρ=-0.19), while Murray's femoral head ratio (ρ=0.05; P=0.274) was not associated with age. Interestingly, the parameters describing the acetabulum all showed a relevant increase in coverage with age, leading to CE-angles well beyond 40° and a Sharp's angle below 35° in a large portion of asymptomatic older adults. Conclusion: While a decrease in CCD angle with age is described in most orthopedic textbooks, the changes observed with age in acetabular geometry far exceed those measured at the femoral head-neck junction. We recommend considering these alterations that may be attributable to age when formulating a radiographic diagnosis. ***Level of Evidence III, Diagnostic Studies – Investigating a Diagnostic Test.***

Keywords: Hip dysplasia. Femoroacetabular impingement. Pelvis. Radiography. Osteoarthritis.

RESUMO

Objetivo: Embora tenham sido estabelecidos vários parâmetros radiográficos para descrever a geometria e a patologia do quadril, seus valores de referência e significância clínica continuam sendo uma questão controversa. O presente estudo testa a hipótese de que a idade tem impacto relevante sobre os parâmetros radiográficos do quadril. Método: As vistas pélvicas anteroposteriores foram medidas quanto ao ângulo CE, ângulo de Sharp, proporção entre profundidade e largura acetabular, índice de extrusão da cabeça do fêmur, obliquidade do lábio do acetábulo (teto), ângulo cabeça-colo-diafisário (CCD) e razão da cabeça do fêmur de Murray e os valores obtidos foram correlacionados com a idade. Resultados: Foram observadas correlações lineares significantes, fracas e moderadas (todos os P < 0,001) entre idade e ângulo CE (ρ = 0,31), ângulo de Sharp (ρ = -0,38), índice de extrusão da cabeça do fêmur (ρ = -0,22), ângulo CCD (ρ = -0,15), proporção entre profundidade e largura acetabular (ρ = -0,38) e obliquidade do lábio do acetábulo (ρ = -0,19), enquanto a razão da cabeça do fêmur de Murray (ρ = 0,05; P = 0,274) não foi associada à idade. Curiosamente, todos os parâmetros que descrevem o acetábulo mostraram um aumento relevante de cobertura com idade, levando a ângulos CE bem além de 40° e ângulos de Sharp abaixo de 35° em uma grande parcela de idosos assintomáticos. Conclusão: Embora a diminuição do ângulo CCD com a idade seja descrita na maioria dos livros didáticos de ortopedia, as alterações na geometria acetabular observadas com a idade ultrapassam, de longe, as medidas na junção entre cabeça e colo do fêmur. Recomendamos considerar essas alterações que podem ser atribuídas à idade ao formular um diagnóstico radiográfico. ***Nível de Evidência III, Estudos Diagnósticos – Investigação de um Exame para Diagnóstico.***

Descritores: *Displasia pélvica. Impacto femoroacetabular. Pelve. Radiografia. Osteoartrite.*

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INTRODUCTION

Wiberg center-edge (CE) angle <25°, femoral head extrusion index >25%, Sharp's angle >40°, acetabular roof obliquity angle >10°, and acetabular roof obliquity angle >10° have been established as a classic sign of hip dysplasia,[1,2] a predominant prearthrotic deformity. In recent years, other changes in hip geometry have been added to describe pathological anatomy of the hip joint. Terms such as excessive overcoverage, acetabular retroversion, and abnormal head-neck junction ("pistol-grip deformity") are now the focus of scientific interest. These anatomical changes can cause two forms of femoroacetabular impingement (FAI) leading to early hip pain and osteoarthritis (OA):[3-6] increased acetabular coverage ("pincer impingement") causes damage at the acetabular rim, and an enlarged femoral neck ("cam impingement") destroys the antero-superior area of the acetabulum.[4,7] After detailed physical examination, a diagnosis of hip dysplasia or FAI is largely based on appropriate imaging. Different radiographic parameters in pelvic antero-posterior views have been established to detect these pathologies. Some have become quite popular over the past few years, such as the "pistol-grip deformity," which is quantified as Murray's femoral head ratio.[8-10]

In these conditions, over time progressive degenerative changes lead to osteophytes, narrowing of the joint space, subchondral sclerosis, and deformity of the bone ends, which in turn have a negative impact on the different radiographic parameters themselves.[11] When evaluating radiographic parameters, however, age also needs to be considered as a factor. The caput-collum-diaphyseal (CCD) angle, for example, is known to decrease significantly with increasing age.[12] Moreover, aged cartilage usually shows non-progressive changes: decreased cellularity, reduced proteoglycan concentration, and reduced mechanical properties. The present study was performed to investigate the hypothesis that not only OA, but also age itself has an impact on different radiographic parameters used to describe hip dysplasia or FAI.

MATERIAL AND METHODS

We analyzed our data bank for all pelvic views performed in our institution between January 1, 2006 and December 31, 2011. The images were analyzed by a specialist registrar from our Department of Radiology. To avoid the negative influence of pelvic tilt and rotation on radiographic parameters, we included only standardized pelvic antero-posterior radiographs in the measurements. The mean distance between the tip of the coccyx and the middle of the symphysis was 32 mm for men and 47 mm for women, and the teardrop sign appeared to be symmetrical.[3] To evaluate the severity of OA of the hip, we used the classification by Kellgren and Lawrence. Only radiographs with no signs of OA of the hip (Kellgren and Lawrence 0) were included in the present study. The pelvic antero-posterior views were measured for CE angle, Sharp's angle, acetabular depth-to-width ratio, femoral head extrusion index, acetabular roof obliquity angle, CCD angle, and Murray's femoral head ratio[8,10,13-17] (for details concerning the measurement of these parameters, see Figure 1). Alpha-angle was not evaluated since recent studies have shown only a limited reliability for conventional radiographs and recommended it for 3D imaging techniques instead (reviewed by Sutter et al.[18]). In cases with unilateral total hip arthroplasty, fracture, or dysplasia (Crowe II-IV),[19] only the contralateral side was measured.

Full approval was obtained from the departmental, institutional, and ethical review boards (project number 025/2014R) before the study began. Due to the retrospective character of the study, no informed consent was obtained.

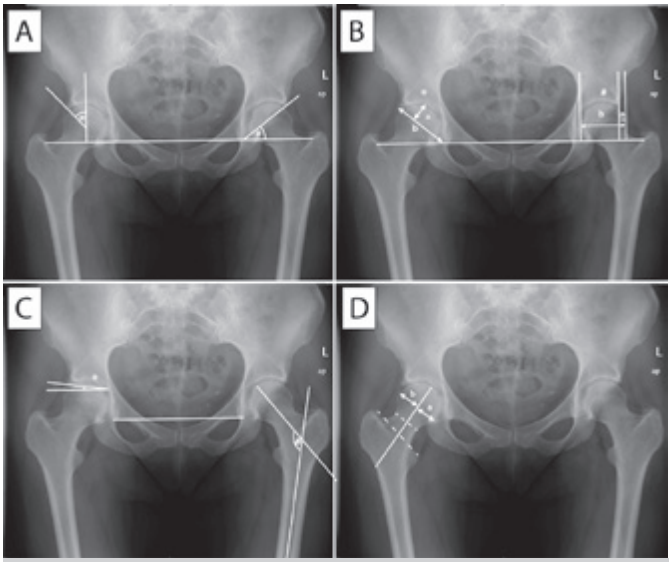

Figure 1. Measured radiographic parameters. ap = antero-posterior; L = left. A) *Wiberg's center-edge angle is defined as the angle between a line perpendicular to the horizontal teardrop line drawn through the center of the femoral head and a line from the center of the head to the lateral rim of the acetabulum. #Sharp's angle describes the angle formed by the horizontal teardrop line and a line from the inferior teardrop point to the lateral edge of the acetabulum. B) *The acetabular depth-to-width ratio is the ratio formed by the distance between the inferior teardrop point and the lateral acetabular rim (width) and the maximum perpendicular distance from this line to the acetabular wall (depth). #The femoral head extrusion index is the percentage of the femoral head that extrudes beyond the acetabular edge on a teardrop line plane (a:b). C) *The acetabular roof obliquity angle is formed by the line connecting the inferior-most edge of the roof of the acetabulum to the lateral-most edge of the acetabulum with a line parallel to the teardrop line. #The caput-collum-diaphyseal angle is measured between the longitudinal axes of the femoral shaft and neck. D) Murray's femoral head ratio is created by drawing a line through the middle of the femoral neck and the middle of the line connecting the apices of the greater and lesser trochanter. The perpendicular maximum distance from this line to the limit of the femoral head on each side is measured and the inferior distance divided by the superior distance (a:b).

Statistical analysis

In order to account for repeated measurements of both hips on the patient level, we conducted analyses by using summarized values for both sides. Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations. The strength of linear associations between age and radiographic parameters was assessed by Pearson's correlation coefficient (ρ). Linear or logistic regression analyses were conducted to describe the influence of age on the radiographic measurements. We considered the influence of possible confounding factors by calculating the corresponding odds ratio (OR) and 95% confidence interval (CI). Because of the descriptive character of the study, no alpha adjustment was performed with a two-sided significance level of 0.05. Statistical analyses were conducted using SPSS version 21 (IBM Corp., Armonk, NY) and R software, version 3.1.0 (R Foundation for Statistical Computing, Vienna).

RESULTS

Of all the pelvic radiographs performed in our institution between January 1, 2006 and December 31, 2011, those of 525 patients met all inclusion criteria. In 245 patients both sides were measured, and in 280 patients only the left (n=122) or right side

(n=158) was measured, totaling a sample of 770 hip joints. The mean patient age was 50.6 (± 18.8) years; 48% of patients were male and 52% female. Protrusio acetabuli was detected in 4 hip joints, coxa profunda in 170 hip joints, and positive cross-over sign in 120 hip joints.

Significant weak or moderate linear associations (all Ps<0.001) were observed between age and CE angle (ρ=0.31), Sharp's angle (ρ=-0.38), acetabular depth-to-width ratio (ρ=-0.38), femoral head extrusion index (ρ=-0.22), acetabular roof obliquity angle (ρ=-0.19), and CCD angle (ρ=-0.15). Murray's femoral head ratio was not associated with age (ρ=0.05; P=0.274). (Table 1 and Figures 2 and 3) Linear regression analysis revealed a small negative effect of age on Sharp's angle (β=-0.10), acetabular depth-to-width ratio (β=-0.10), femoral head extrusion index (β=-0.09), acetabular roof obliquity angle (β=-0.05) and CCD angle (β=-0.06), and a small positive effect on CE angle (β=0.15; each P<0.001) (Table 2). These results imply that age has a weak-to-moderate impact on the different radiographic parameters for FAI and hip dysplasia. No statistically significant influence of age on Murray's femoral head ratio (β=0.00; P=0.274), protrusio acetabuli (left side: OR=1.03, 95% CI 0.95 to 1.12; right side: OR=1.04, 95% CI 0.97 to 1.14), coxa profunda (left and right sides: OR=0.99, 95% CI 0.98 to 1.01), or cross-over sign (left and right sides: OR=1.01, 95% CI 0.99 to 1.02) could be observed.

Table 1. Measurement values for the different radiographic parameters.

Hip parameter (n=770)	Mean (standard deviation)
Wiberg's CE angle	35.81° ± 9.56°
Sharp's angle	36.65° ± 4.79
Acetabular depth-to-width ratio	58.57% ± 7.94
Femoral head extrusion index	14.63% ± 8.04
Acetabular roof obliquity angle	9.49° ± 5.21°
CCD angle	133.36° ± 8.71°
Murray's femoral head ratio	1.09 ± 0.22

CE - center-edge; CCD - caput-collum-diaphyseal.

DISCUSSION

Hip dysplasia with reduced CE angle, decreased depth-to-width ratio, and increased extrusion index is widely accepted as the main reason for OA in young adults.[11,13,20] Recently, other changes in acetabular geometry with excessive local or global overcoverage and reduced head-neck offset have been detected as further major causes for progressive hip pain and early OA of the hip. However, the predictability of these findings for early OA onset remains a matter of debate. On the one hand, abnormal hip morphology with either "classic" acetabular dysplasia or impingement due to excessive overcoverage of the femoral head, acetabular retroversion, or an abnormal head-neck junction has been reported in approximately 51%–97% of all cases of hip OA.[9,13] On the other hand, Laborie et al.[9] demonstrated a prevalence of radiographic findings for FAI in the majority of a cohort of 2081 healthy adults. De Bruin et al.[21] found only 58 hip radiographs devoid of signs for FAI in a sample of 522 hips not clinically suspected of FAI. This leaves room to discuss the extent to which these parameters can be used as predictive factors for OA. Some of these findings may also be a consequence of early OA onset. For example, whether the posterior head tilt in osteoarthritic hips should be considered an acquired deformity created by the formation of osteophytes is currently under discussion. This has led to the suggestion that radiographic signs to detect FAI and hip dysplasia should be used carefully in patients with OA of the hip.[11]

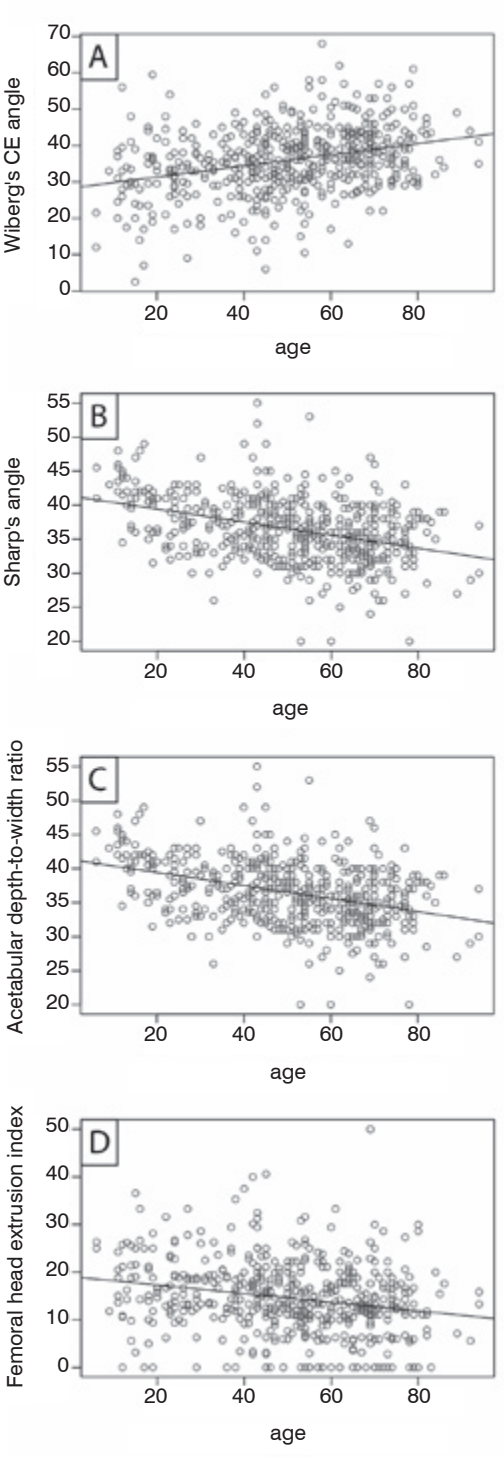

Figure 2. Pearson correlations between age and (A) Wiberg's center-edge (CE) angle, (B) Sharp's angle, (C) acetabular depth-to-width ratio, and (D) femoral head extrusion index.

The present study was performed to assess the impact of age itself on various radiographic parameters used to diagnose FAI and hip dysplasia. We showed that age has a significant influence on many of these measurements. With respect to the strength of the correlations with age, it is noteworthy that the decrease in CCD angle with age is described in most orthopedic textbooks.

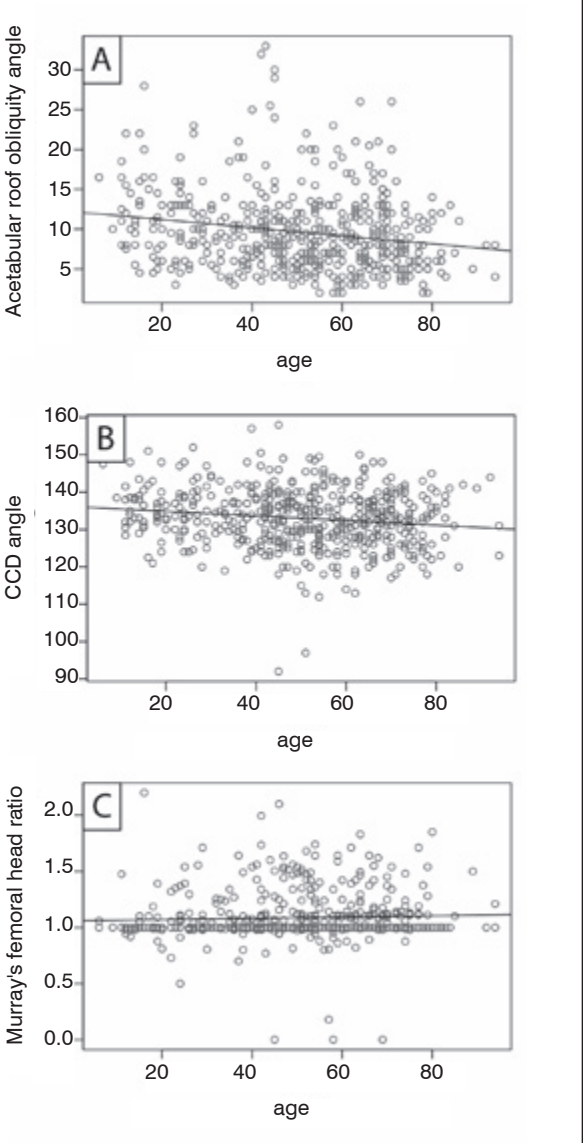

Figure 3. Pearson correlations between age and (A) acetabular roof obliquity angle, (B) caput-collum-diaphyseal (CCD) angle, and (C) Murray's femoral head ratio.

Table 2. Correlations and linear regression analyses of the effect of age on radiographic hip parameters.

Hip parameter (n=770)	Pearson correlation	Linear regression analysis
Wiberg's CE angle	ρ=0.31, P<0.001	β=0.15, P<0.001
Sharp's angle	ρ=-0.38, P<0.001	β=-0.10, P<0.001
Acetabular depth-to-width ratio	ρ=-0.38, P<0.001	β=-0.10, P<0.001
Femoral head extrusion index	ρ=-0.22, P<0.001	β=-0.09, P<0.001
Acetabular roof obliquity angle	ρ=-0.19, P<0.001	β=-0.05, P<0.001
CCD angle	ρ=-0.15, P<0.001	β=-0.06, P<0.001
Murray's femoral head ratio	ρ=0.05, P=0.050	β=0.00, P=0.274

CE - center-edge; CCD - caput-collum-diaphyseal.

Nevertheless, except for the non-correlating Murray's head-neck ratio, CCD angle showed the weakest correlation of all parameters analyzed (ρ=-0.15) in this study. It is noteworthy that while CCD angle and Murray's head-neck ratio describe femoral changes, the parameters with much stronger correlation are all linked to the shape of the acetabulum.

So far it is well known that Wiberg's CE angle increases during skeletal growth. In adults, however, only a very weak increase has been described.[22] The increase in acetabular coverage might seem accidental when just looking at one single parameter. The values observed are, however, all coherent. Just as Wiberg's angle increases due to better coverage, Sharp's angle, the acetabular roof obliquity angle, and the femoral head extrusion index decrease. And even though clinical experience might indicate that higher depth-to-width ratios are observed in older people (as in an osteoarthritic coxa profunda, for example), this conjecture is deceiving, since it only applies to osteoarthritic hip joints. With an increase in acetabular coverage, the resulting increase in width of the fossa exceeds the increase in depth, leading to a decrease of the ratio. How the radiological increase in acetabular coverage is produced still needs to be clarified. One possible explanation might be ossification of the labral base[23] leading to false interpretation of the actual acetabular rim. It is more likely, however, that in the zone of maximum biomechanical stress the pelvis reacts over time by strengthening the apical zone. It is essential to realize that this acetabular increase leads to CE-angles well beyond 40° and a Sharp's angle below 35° in a large portion of elderly people. These radiographic angles would usually be considered as FAI,[7,16] but remain asymptomatic in many cases. Since the long-term outcome of surgical resurfacing of the head-neck junction still varies widely, we suggest considering age-related alterations before formulating a radiographic diagnosis from measured values.

Study limitations

Some degenerative changes can almost always be observed in pelvic radiographs of older patients with hip pain. It is consequently difficult to make a clear distinction between whether these changes are attributable to ageing of the joint or to degeneration. In this study, however, only radiographs of patients not diagnosed with or treated for OA were included to minimize this effect. We did not test intra- or inter-observer reliability, although strong inter- and intra-observer discrepancies are known to occur in radiographic measurements to diagnose dysplasia and FAI. Even so, the lack of this evaluation should not have affected our results, since the only observer was blinded to patient age and considered all cases equally. Certain hip parameters may also be affected by a change in posture in elderly patients, but such a change in postural pelvic orientation would also affect joint function. Possible differences due to different projection angles in the radiographs may be solved in the future by using three-dimensional imaging techniques with volume renderings.

CONCLUSION

Patient age has a relevant impact on various radiographic parameters to detect FAI and hip dysplasia. While femoral CCD angle decreases only marginally, acetabular coverage increases considerably over time. Although these changes are in many cases negligible, especially when borderline values are found, alterations that may be attributable to age should be considered.

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ORIGINAL ARTICLE

PROFILE OF PATIENTS RECEIVING TOTAL KNEE ARTHROPLASTY: A CROSS-SECTIONAL STUDY

PERFIL DE PACIENTES SUBMETIDOS À ARTROPLASTIA TOTAL DE JOELHO: UM ESTUDO TRANSVERSAL

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ABSTRACT

Objective: To describe the epidemiological profile, presented deformities, associated comorbidities, and impact on quality of life in patients with knee osteoarthritis. This study was conducted in a philanthropic hospital in Fortaleza from 2014 to 2015. Methods: Data were collected from medical records, epidemiological forms, and by applying the Lequesne index questionnaire, which contains several questions related to pain, discomfort and functional limitation to assess the severity of symptoms. Results: Females were more prevalent (76.7%), as were patients over 65 years of age (61.6%) and non-whites (81.6%). As for comorbidities, 83.3% had hypertension and 31.7% had diabetes. Of the total, 76.5% cases were genu varum, and 23.5% genu valgum. According to the Lequesne index findings, 61.6% cases were "extremely severe," and women had higher scores. Conclusion: Females were more prevalent and whites were less prevalent. The most frequent comorbidity was hypertension. Female and elderly patients have more severe disease according to Lequesne index score, and these findings were statistically significant. ***Level of Evidence II, Prospective Study.***

Keywords: Arthroplasty. Knee. Osteoarthritis.

RESUMO

Objetivo: Descrever o perfil epidemiológico, as deformidades, comorbidades associadas e o impacto sobre a qualidade de vida de pacientes com osteoartrite de joelho. O estudo foi realizado em um hospital filantrópico de Fortaleza, no período de 2014 a 2015. Métodos: A coleta de dados foi realizada a partir de análises de prontuários, uso de formulários epidemiológicos e aplicação do questionário de Lequesne, que tem várias questões sobre dor, desconforto e limitação funcional, para avaliar a gravidade dos sintomas. Resultados: Houve maior prevalência do sexo feminino (76,7%), de pacientes com mais de 65 anos (61,6%) e das raças não brancas (81,6%). Sobre comorbidades, 83,3% tinham hipertensão arterial, 31,7% tinham diabetes. Do total, 76,5% tinham geno varo e 23,5%, geno valgo. De acordo com o questionário de Lequesne, 61,6% tinham quadro "extremamente grave", sendo as mulheres as que tiveram maior pontuação. Conclusão: O sexo feminino foi o mais prevalente. A raça branca foi a menos prevalente. A comorbidade com maior incidência foi a hipertensão arterial. O sexo feminino e os pacientes mais idosos apresentam maior gravidade da doença, segundo o questionário de Lequesne. Esses achados foram estatisticamente significantes. ***Nível de Evidência II, Estudo Prospectivo.***

Descritores: *Artroplastia. Joelho. Osteoartrite.*

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INTRODUCTION

The growing number of procedures such as arthroplasty results from a number of factors such as the aging of the population, the increasing prevalence of rheumatoid arthritis, and increased numbers of obese patients.[1,2] Total knee arthroplasty (TKA) is considered to be among the most successful types of orthopedic surgery, since even after 15 years implant survival exceeds 95%; furthermore, the improvement in quality of life is very significant.[3-5]

The main cause in most patients who undergo this procedure is osteoarthrosis.[6,7]

Studies suggest that Brazil will have the fifth-largest population on the planet in 2050,[8] indicating that the frequency of TKA may increase over the next 30 years.

In order to understand the patients who undergo TKA to treat osteoarthritis (OA), this study collected Lequesne scores and a variety of data including epidemiological information from all patients with OA who were recommended for surgical treatment at the outpatient orthopedics clinic at Hospital Santa Casa de Misericórdia de Fortaleza.

All authors declare no potential conflict of interest related to this article.

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MATERIALS AND METHODS

This transversal, descriptive study is based on quantitative data. It was carried out between January 2014 and January 2015 at the Santa Casa de Misericórdia de Fortaleza charity hospital. We included patients with osteoarthritis who were referred for surgical treatment and signed the informed consent form. Exclusion criteria were lack of data in the medical records and non-agreement to sign the informed consent form. The study was approved by the institutional review board under number CAAE 44595315.1.0000.5049.

Initially data such as sex, race, origin, diagnosis, and presenting deformity were collected from the patient medical records for analysis. In addition, patients filled out an epidemiological form developed by the researchers (Annex 1) which collected data such as age, profession, smoking and drinking habits, wait time prior to surgery, and associated comorbidities such as hypertension and diabetes mellitus. Next, the Lequesne index questionnaire was applied prior to surgery. This questionnaire assesses pain and functional limitation and classifies patients by score. The severity of the disease in the patient can be classified as follows: "mild" (1–4 points), "moderate" (5–7 points), "severe" (8–10 points), "very severe" (11–13 points) and "extremely severe" (≥14 points). (Annex 2) For uniform application of the questionnaires, the researchers were trained prior to administration.

The patients were recommended for surgical treatment after physical examination and imaging exams performed by orthopedic physicians and radiologists. At no time during this study did these physicians know the Lequesne index scores for their patients.

The statistical analysis was performed using the IBM SPSS Statistics software, version 20.0.0. A 5% significance level was adopted, and the chi-square hypothesis test was used to investigate the association between categorical variables and the distribution of the sample. P-values <0.05 were considered statistically significant.

RESULTS

The initial sample consisted of 152 patients; at the end of the study, the sample was reduced to 60 patients with knee OA because of missing information in the medical records and loss to follow-up. Women comprised 76.6% of the sample and men 23.3% (Table 1). Women were seen to be more affected according to Lequesne index score (P=0.034). Patients aged over 65 years were 61.6% of the sample, and 38.3% were in the 55–65 age range. Application of Pearson's correlation coefficient showed that this correlation was significant (P=0.035) and the relationship was positive, demonstrating that increased age means higher index scores, and consequently the patient is more seriously affected (Table 2).

As for comorbidities, 83.3% of the patients had hypertension, 31.7% had diabetes, and 26.7% had hypertension and diabetes. Of all the patients with a Lequesne score >14 ("extremely severe"), 78.3% had hypertension and 21.6% did not (Table 3); 8.3% had knee OA secondary to rheumatoid arthritis. With regard to alcohol and tobacco use, 20% of the patients drank alcohol and 16.7% were smokers. No significant connection was found between these habits and disease severity as measured by the Lequesne scores.

Table 1. Severity according to sex.

	Extremely severe	Very severe	Severe	Moderate
Total sample	**61.6%**	**30%**	**6.6%**	**1.6%**
Females P=0.034	53.3%	20%	1.6%	1.6%
Males	8.3%	10%	5%	0%

Table 2. Severity according to age.

P=0.035	Extremely severe	Very severe	Severe	Moderate
55–65 years	23.3%	11.66%	3.3%	0%
>65 years	38.33%	18.33%	3.3%	1.6%

Table 3. Comorbidities and disease severity.

	Hypertension	Diabetes	Hypertension and diabetes
Total sample	84.9%	31.7%	26.7%
Extremely severe	48.3%	23.3%	18.3%
Very severe	28.3%	6.7%	6.7%
Severe	6.7%	1.7%	1.7%
Moderate	1.6%	0%	0%

Of the total, 76.5% of cases were genu varum and 23.5% genu valgum. According to the Lequesne index, 61.6% of the cases were classified as "extremely severe," 30% as "very severe," 6.6% as "severe," and 1.6% (only one patient) as "moderate." All patients who had OA secondary to rheumatoid arthritis had very high scores, such as 21 points. The highest patient score was 23 points, the lowest score was 7, and the average was 15.53. We also obtained information about wait time for each patient prior to surgery, which ranged from <1 year for 15% of patients and 1–5 years for 81.6% of patients to >5 years for 3.3% of patients.

DISCUSSION

Many Brazilian studies involving patients who received TKA have found a high prevalence of female patients with an average age ranging from 69 to 79 years.[6,9,10] As for race, the studies in Brazil are limited. International studies have found that non-whites (namely mixed-race people of African descent and Blacks) have more functional limitation due to OA, and non-white women are two times more likely to have knee OA.[11-13] The present study found a greater prevalence of females (76.7%), patients over age 65 (61.6%), and non-white patients (81.6%), which is in line with most international studies. However, the Lequesne scores did not show that non-white patients were more affected than whites. The Lequesne questionnaire confirmed that women are more affected (P<0.05); 95.6% of the women were classified as having extremely severe or very severe cases. Furthermore, the Lequesne index showed that older patients were more severely affected (P<0.05).

Some comorbidities such as hypertension and diabetes were frequently present in patients in this study. The use of NSAIDs by a number of patients with OA may have elevated blood pressure.[14] Furthermore, both hypertension and diabetes are described as having an impact in the pathophysiology of OA, and diabetes is currently considered a risk factor for progression of knee OA.[15] Hypertension was the most frequent comorbidity, in 83.3% of the sample, followed by diabetes. Previous studies conducted in Brazil found a lower prevalence of hypertension, ranging from 59% to 81%, and diabetes ranging from 19% to 35%.[6,9,16]

Some international studies have described alcohol consumption as often relieving symptoms in patients with OA, but we are very familiar with the risks of this habit in the population in general.[17] Moreover, recent studies have shown that drinking alcoholic beverages such as beer increases the risk of osteoarthritis.[18] The current study found alcohol consumption in 20% of the sample. Perhaps the fact that most of the sample was female influenced this finding, since the female population is known to drink less alcohol than men. In order to confirm whether there was any relationship between drinking alcohol and the severity of OA, patients who consumed alcohol were correlated with Lequesne scores, but the outcome was not statistically significant (P>0.05).

Some years ago there were some doubts about the effects of cigarette smoking on patients with OA, but a recent meta-analysis showed that smoking did not have a protective effect.[19] In our study, the prevalence of smokers was low (16.7%).

Recent studies show that bow-leggedness increases the incidence of OA and increases the progression of medial OA, so an increased prevalence of genu varum is expected in patients with OA of the knee.[20] In the present study, more than 75% of the patients had the genu varum deformity.

The Lequesne questionnaire was developed in France in the 1970s and updated in 2003; it is used often in Europe and contains several questions for patients to answer about pain, discomfort and function, evaluating the severity of symptoms and degree of physical handicap.[21] The Lequesne index, unlike other questionnaires, is quick and easy to apply, and non-subjective. It does not contain questions specific to the population of a given country and can therefore be used in any population. It is intended for patients with OA, and is brief, so responding is not difficult. Furthermore, it is difficult for patients to manipulate their score for their own benefit on this questionnaire, since they do not know which type of response has a higher point value.

Of the total sample, 61.6% of cases were classified as "extremely severe" with a score >14. Of the total, 30% of the sample was considered "very severe," 6.6% "severe," and 1.6% "moderate." The mean score was 15.53. The high score is consistent, because all these patients were referred for surgical treatment. Other patients with very high scores had rheumatoid arthritis as well as OA, and comprised 8.3% of the total.

We also noted that although these patients were more severely affected according to their score, they faced a long wait time for surgery since few slots are available; slightly over 80% needed to wait 1–5 years for surgery.

CONCLUSION

Most patients who seek medical help for this problem are over 65 years of age. Females were more prevalent, and whites were least prevalent. The most frequent comorbidity was hypertension. Lequesne index scores were higher in females and in the older patients in the sample, with statistically significant findings. The Lequesne scores for each patient were consistent with degree of severity recognized by the orthopedists and radiologists who recommended surgical treatment.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. MJCB (0000-0001-8629-5417)*, IMB (0000-0002-0051-7734)*, LMF (0000-0002-9208-5667)*, and TGS (0000-0003-0212-3728)* drafted the manuscript. MJCB performed surgeries and was responsible for outpatient care. IMB, MJCB, LMF, TGS, LMH (0000-0003-2960-9170)*, and DLMM (0000-0002-5679-9566)* followed the patients, collected data, and applied the Lequesne index questionnaire. IMB and MJCB evaluated the data from the statistical analysis. All authors performed the bibliographic research, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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Annex 1. Patient Profile Form.

1) Patient Identification:
• Name:
• Age:
• Sex: ( ) F ( ) M
• Color/Race: ( ) White ( ) Black ( ) Mixed race

2) Deformity (according to chart)? Varus ( ) ou Valgus ( )

3) Social History
• Smoking:
( ) no ( ) yes (how many cigarettes per day? ____)

• Alcohol consumption:
( ) no ( ) yes (how many glasses/bottles per day? ____)

4) Does patient take any medication (for some previous disease)?
( ) yes ( ) no If yes, what?_____

5) Past Disease History:
• Patient had: ( ) Hypertension ( ) Diabetes ( ) Rheumatoid Arthritis ( ) other which:_____

6) How long did patient wait for surgery? _____

Annex 2. Algofunctional Lequesne Questionnaire

Pain or Discomfort
• During sleep at night:
- none or insignificant: 0
- only when moving or in certain positions: 1
- even without movement: 2

• morning stiffness or pain that decreases after getting up
- 1 minute or less: 0
- more than 1 minute, but less than 15 minutes: 1
- more than 15 minutes: 2

• after walking for 30 minutes 0 - 1

• while walking
- none: 0
- only after walking some distance: 1
- soon after beginning to walk, and increases if you continue to walk: 2
- after beginning to walk, not increasing: 1

• when remaining seated for a long time (2 hours) (only if hip) 0 - 1

• when rising from a chair without using the armrests (only if knee) 0 - 1

Maximum distance walked (can walk with pain):
- unlimited: 0
- more than 1 km, but with some difficulty: 1
- approximately 1 km (in + or - 15 minutes): 2
- from 500 to 900 meters (approximately 8 to 15 minutes): 3
- from 300 to 500 meters: 4
- from 100 to 300 meters: 5
- less than 100 meters: 6
- with a cane or crutch: 1
- with two crutches or canes: 2

Daily activities/daily life (only applies to knee)*
- can climb a flight of stairs: 0 – 2*
- can go down a flight of stairs: 0 – 2*
- squat or kneel: 0 – 2*
- can walk on uneven ground: 0 – 2*

*Without difficulty: 0, With little difficulty: 0.5, With difficulty: 1, With significant difficulty: 1.5, Unable: 2.

Point scoring:

Extremely severe (greater than or equal to 14 points), Very severe (11 to 13 points), Severe (8 to 10 points), Moderate (5 to 7 points), Mild involvement (1 to 4 points).

Source. Marx FC, Oliveira LM, Bellinil CG, Ribeirol MCC. Tradução e validação cultural do questionário algofuncional de Lequesne para osteoartrite de joelhos e quadris para a língua portuguesa. Rev Bras Reumatol. 2006;46(4):253-60.

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ORIGINAL ARTICLE

COMPARED EFFICACY OF INTRA-ARTICULAR INJECTION OF METHYLPREDNISOLONE AND TRIAMCINOLONE

COMPARAÇÃO DE EFICÁCIA DE INJEÇÃO INTRA-ARTICULAR DE METILPREDNISOLONA E TRIANCINOLONA

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ABSTRACT

Objective: To compare the effect of two different corticosteroid types in bilateral and symmetrical knee osteoarthritis (OA). Methods: One hundred and twenty-six patients received injections of methylprednisolone acetate (MP) in one knee and triamcinolone hexacetonide (TH) in the contralateral knee. Patients were evaluated before injection and 2, 4, 8, 12, and 24 weeks after. Results: Mean patient age was 68.5±9 years. Mean BMI was 26.3±2.6 kg/m^2. At first admission, mean VAS score was 7.7±1.3 for the right side and 7.5±1.5 for the left side, and mean WOMAC score was 67.6±14.4. After bilateral intra-articular injection, VAS scores for both knees and WOMAC scores decreased significantly when initial scores were compared with 2, 4, 8, 12, and 24 weeks after injection ($p<0.05$). A statistically significant change was seen over time when VAS and WOMAC scores for 2, 4, 8, 12, and 24 weeks post-injection were compared to each other ($p<0.05$). No significant difference was seen between knee sides ($p>0.05$). Conclusion: MP and TH have similar efficacy in relieving pain and improving function. The efficacy of intra-articular corticosteroid injection peaks 2 weeks after injection and the effect continues until the 24th week. ***Level of Evidence II, Comparative Prospective Study.***

Keywords: Osteoarthritis, knee. Injections, intra-articular. Methylprednisolone/administration & dosage. Triamcinolone. acetonide/administration & dosage.

RESUMO

Objetivo: Comparar o efeito de dois tipos de corticosteroides em osteoartrite (OA) de joelho bilateral e simétrica. Métodos: Cento e vinte e seis pacientes receberam injeções de acetato de metilprednisolona (MP) em um joelho e de triancinolona hexacetonida (TH) no joelho contralateral. Os pacientes foram avaliados antes da injeção e 2, 4, 8, 12 e 24 semanas depois. Resultados: A média de idade dos pacientes foi 68,5 ± 9 anos. O IMC médio foi 26,3 ± 2,6 kg/m^2. Na primeira internação, o escore médio da EVA foi 7,7 ± 1,3 para o lado direito e 7,5 ± 1,5 para o esquerdo e a média do escore WOMAC foi 67,6 ± 14,4. Depois da aplicação bilateral das injeções intra-articular, os escores da EVA e do WOMAC para ambos os joelhos diminuíram significantemente ao comparar os escores iniciais com os de 2, 4, 8, 12 e 24 semanas depois da injeção ($p < 0,05$). Constatou-se diferença estatisticamente significante no decorrer do tempo, quando os escores EVA e WOMAC às 2, 4, 8, 12 e 24 semanas depois da injeção foram comparados entre si ($p < 0,05$). Não houve diferença significante entre os lados direito e esquerdo ($p > 0,05$). Conclusão: MP e TH têm eficácia similar quanto ao alívio da dor e à melhora da função. A eficácia da injeção intra-articular de corticosteroides atinge o máximo duas semanas depois da aplicação e o efeito continua até a 24ª semana. ***Nível de Evidência II, Estudo Prospectivo Comparativo.***

Descritores: *Osteoartrite do joelho. Injeções intra-articulares. Metilprednisolona/administração & dosagem. Triancinolona acetonida/administração & dosagem.*

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INTRODUCTION

Osteoarthritis of the knee is a major cause of pain and disability in older adults.[1] Pain control is one of the main goals in treating knee OA.[2] Management of this disease begins with conservative treatment such as physical therapy, exercise, weight loss, and medications; surgical intervention can be indicated for patients with advanced OA.[3] Intra-articular corticosteroid injections (IACI) are frequently used and recommended by the American College of Rheumatology as part of conservative therapy for knee OA.[4] The clinical benefits of IACI have been evaluated in several studies.[5-7] Some studies have raised concerns about progression of cartilage destruction, but others have shown that corticosteroid injections can reduce this progression.[8,9] The literature describes various inconsistent results from IACI; although some studies suggest short-term benefits (usually for one

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to four weeks), others suggest benefits may last up to 24 weeks.[10,11] Some studies also have compared different types of corticosteroids for intra-articular injection. The perceived efficacy and rare adverse effects have made IACI a mainstay of knee OA management.[12,13] Methylprednisolone acetate and triamcinolone hexacetonide are the most commonly used intra-articular corticosteroids.[14]

This present study consists of a randomized, prospective, multicenter investigation to determine the effect of two different types of corticosteroids on OA; this comparison was made by injecting bilateral and symmetrical knee joints involved with the two most commonly used compounds.

MATERIAL AND METHODS

After written consent was obtained from all patients and approval by the institutional review board (process number 10840098-604.01,01-E.3351, 1/3/2016), 126 patients (101 female, 25 male) were included in the study.

All patients presented to the outpatient orthopedic clinic with a bilateral knee pain score of ≥4 points on a 0–10 Visual Analog Scale (VAS) on the day of the examination. Patients were also required to have radiologically verified bilateral grade 3 OA of the knee according to the Kellgren-Lawrence classification.[15] All patients in this study had dissatisfaction with previous attempts at conservative treatment including non-steroidal anti-inflammatory drugs.

Exclusion criteria were: secondary arthritis, joint instability, IACI within the previous 6 months, history of diabetes mellitus, recent history of trauma to the knee, BMI >30, or presence of cancer or malignant disorders. Patients were also excluded if they had contraindications to injection, such as infection, anticoagulation therapy, allergy or hypersensitivity to any of the study medications. Patients who used systemic corticosteroids were also excluded, as were patients with a difference of >2 points between their knees on the VAS.

In this study we did not use a control group. Instead, we compared the medications by injecting methylprednisolone acetate (MP) in one knee and triamcinolone hexacetonide (TH) in the contralateral knee of the same patient. A randomization procedure was followed to assign each compound to the right or the left knee.

Patients were placed in a sitting position with knee flexion of 90 degrees, and a lateral approach to the knee was used. The skin of the injection site was cleaned with povidone-iodine solution. No anesthetic was administered before injection. Either 1 mL of 40 mg methylprednisolone acetate (Depo-Medrol, Pfizer) mixed with 3 mL 1% lidocaine or 2 mL of 40 mg triamcinolone hexacetonide (Artropan, Kocak Farma, 20 mg/mL) mixed with 3mL 1% lidocaine was injected under sterile conditions using a 22G needle. Needles were changed between drawing up the steroid and injection.

Four orthopedic surgeons in three centers applied all of the injections. Additional injections were not permitted during the study period.

A fifth surgeon who was not aware of the study design performed the clinical evaluation. Patients were evaluated before the injection and in control visits 2, 4, 8, 12, and 24 weeks after the injections. Pain severity was evaluated at each visit according to the VAS for each knee, and function was assessed using the WOMAC scale.[16] Possible complications and side effects were also evaluated at each visit.

The statistical analysis was performed using SPSS 22.0 software (IBM Corp., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to assess normal distribution of the variables. The non-parametric Wilcoxon test was used to compare VAS and WOMAC scores at first admission and at 2, 4, 8, 12, and 24 weeks after injection. The non-parametric Mann-Whitney U test was used to compare VAS scores for the right and left sides at 2, 4, 8, 12, and 24 weeks after injection. Analysis of variance (ANOVA) was used to compare repeated measurements of VAS and WOMAC scores at 2, 4, 8, 12, and 24 weeks after injection.

RESULTS

The mean age of the 126 patients was 68.5 ± 9 years (range: 57–83). Mean patient BMI was 26.3 ± 2.6 kg/m^2 (range: 21–30). At first admission; mean VAS score was 7.7 ± 1.3 for right knees and 7.5 ± 1.5 for left knees, and mean WOMAC score was 67.6 ± 14.4. After bilateral intra-articular injection, there was a statistically significant decrease in the initial VAS scores for both knees and WOMAC score in comparison with these measurements taken 2, 4, 8, 12, and 24 weeks after injection ($p<0.05$). (Table 1) We also found a statistically significant change over time when VAS and WOMAC scores from 2, 4, 8, 12, and 24 weeks after injection were compared to each other ($p<0.05$), indicating that the pain relieving effect of both agents decreases over time. (Figure 1) No statistically significant difference was seen in VAS scores taken at first admission and 2, 4, 8, 12, and 24 weeks after injection when the right side (injected with methylprednisolone acetate) was compared with the left side (injected with triamcinolone hexacetonide). ($p>0.05$) (Table 1)

DISCUSSION

Knee OA is a common degenerative joint disease and affects more than one-third of people over age 65.[17] The most common presenting symptom of OA is pain. Two meta-analyses concluded that IACI is clinically and statistically effective in reducing pain.[10,18] The exact mechanism by which intra-articular corticosteroid injection works is not yet clear, but it is thought that corticosteroids inhibit leukocyte secretion from the synovial cells and decrease synthesis of interleukins and prostaglandins.[17] Synovial membranes in OA have been shown to be the source of proinflammatory cytokines that may be responsible for the clinical symptoms and progression of OA via cartilage destruction.[19] A randomized, double-blind placebo controlled study by Raynauld et al.[20] showed that long-term repetitive administration of IACI is effective for symptom relief and has no destructive effect on the anatomical structures of the knee. Our study demonstrated that both intra-articular triamcinolone and methylprednisolone are effective at reducing pain and improving function in patients with knee OA, and their efficacy may last up to 24 weeks. In this study we observed that for patients who benefited from intra-articular injection, both steroid types had similar effects and duration of efficacy. There are studies comparing corticosteroid types in the literature. Pyne et al.[21] reported that triamcinolone was statistically more efficient in pain relief 3 weeks after injection than methylprednisolone. In another study, however, Yavuz et al.[22] stated that methylprednisolone was statistically more effective in relieving pain than other agents including triamcinolone until 6 weeks after injection. In our

Table 1. Mean VAS scores of right and left knee and mean WOMAC scores of the patients.

First admission*			2nd week*			4th week*		
VAS R	VAS L	WOMAC	VAS R	VAS L	WOMAC	VAS R	VAS L	WOMAC
7.7 ± 1.3	7.5 ± 1.5	67.6 ± 14.4	2.3 ± 2.2	1.9 ± 1.8	31.6 ± 17.3	2.5 ± 2.4	2.2 ± 2.1	33.9 ± 19.1
8th Week*			12th Week*			24th Week*		
VAS R	VAS L	WOMAC	VAS R	VAS L	WOMAC	VAS R	VAS L	WOMAC
4.1 ± 2.7	3.7 ± 2.6	46.6 ± 21.8	5.5 ± 2.2	5.2 ± 2.4	58.1 ± 18	5.8 ± 1.9	5.4 ± 2.2	61.3 ± 16.4

* ± standart deviation.

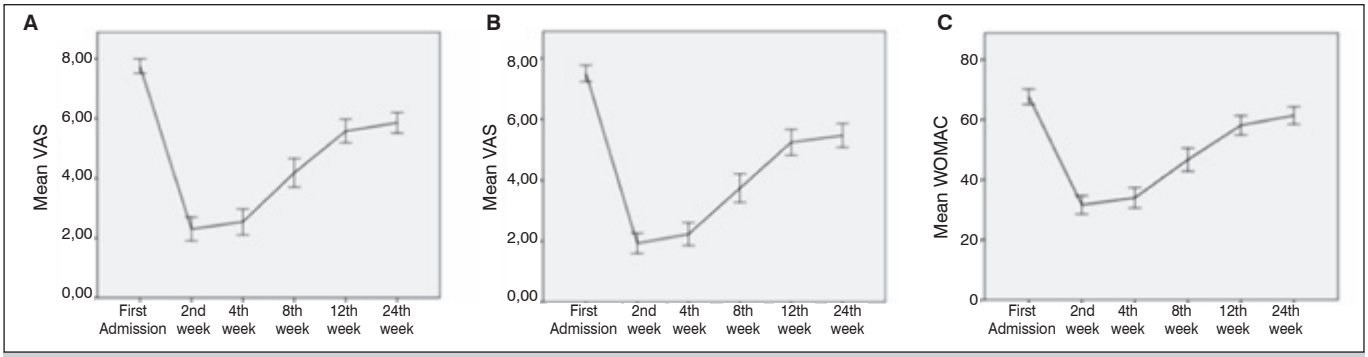

Figure 1. A: Linear graph showing mean VAS scores after injection with methylprednisolone acetate. B: Linear graph of mean VAS scores after injection with triamcinolone hexacetonide. C: Linear graph of mean WOMAC scores for both knees.

own study, no difference was observed between the two types of corticosteroids in terms of pain relief.

Although it is administered locally, a significant portion of the active corticosteroid compound may be absorbed from the joint into the circulation and result in systemic effects. Most of studies in the literature evaluated the hypothalamic-pituitary-adrenal axis. Serum cortisol levels decrease within hours of injection and usually return to recovery level in 1 to 4 weeks, but this may take longer depending on the type and dose of IACI.[23] The most common dose preference for the knee joint varies from 20 to 80 mg methylprednisolone or 20 to 40 mg triamcinolone.[10,24] We used 40 mg triamcinolone and 40 mg methylprednisolone. The most severe complications of IACI are septic arthritis and steroid-induced arthropathy,[25] but the complications are rare.[26] In our study, 19 of 126 patients had mild pain at the injection site which subsided in a day; no patients had any significant adverse effects.

This study was limited by the fact that we investigated only two types of corticosteroids. We investigated the most commonly used agents; other types could yield different results. Another limitation is the use of the VAS, an objective test for evaluating outcomes.

CONCLUSION

In conclusion, bilateral IACI using either methylprednisolone or triamcinolone is safe and effective at reducing pain in patients with bilateral knee OA. Both intra-articular triamcinolone and methylprednisolone have similar efficacy in relieving pain and improving function. The efficacy of IACI is highest 2 weeks after injection and the effect continues to 24 weeks after injection.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. AFB (0000-0003-0316-5444)* and EK (0000-0003-1229-9815)* drafted the manuscript. AFB, EK, and SC (0000-0001-5899-6910)* administered the injections, followed patients, and gathered clinical data. IYC (0000-0002-3900-5162)* and AK (0000-0001-5899-6910)* evaluated the data from the statistical analysis. HU (0000-0001-8394-0708)*, AFB, and EK performed the literature search, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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ANALYSIS OF THE PATTERN AND MECHANISM OF ELBOW INJURIES RELATED TO ARMBAR-TYPE ARMLOCKS IN JIU-JITSU FIGHTERS

ANÁLISE DO PADRÃO E MECANISMO DAS LESÕES DO COTOVELO SUBMETIDO À CHAVE DO TIPO *ARMLOCK* EM LUTADORES DE JIU-JÍTSU

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ABSTRACT

Objective: The objective of this study was to analyze elbow injuries and their probable mechanism in Jiu-Jitsu fighters resulting from the armbar-type armlock. Methods: We evaluated 5 high-performance Jiu-Jitsu fighters from the Gracie Elite gym who were injured during a tournament. All were healthy males with a mean age of 28.8 years. The right arm was involved in three patients (60%). The athletes were followed for approximately 4.6 months, and pain was present in all cases. Clinical examination of the elbow was performed immediately after the injury and when magnetic resonance imaging (MRI) was performed. The radiography showed no changes. Clinical examination detected specific tender points on the medial and anterior topography of the elbows, but no ligamentous instability of the elbow was seen during dynamic testing. Results: The main MRI findings were injury to the common flexor tendon and the ulnar collateral ligament, bone contusion of the distal humerus and olecranon, and joint effusion. Conclusion: The main pattern of injury indicated by the MRI in the athletes was injury to the medial elbow complex. The primary mechanism that determined the injury was most likely elbow hyperextension applied with the forearm in neutral position of forearm. ***Level of Evidence IV, Case Series.***

Keywords: Elbow. Elbow joint. Dislocations. Athletic injuries.

RESUMO

Objetivo: Demonstrar os resultados da análise das lesões do cotovelo e seu provável mecanismo em cinco atletas lutadores de jiu-jítsu decorrentes da chave de braço do tipo armlock. Métodos: Foram avaliados cinco lutadores de jiu-jítsu da academia Gracie Elite, de alto rendimento esportivo, que sofreram lesão durante a realização de um campeonato dessa modalidade. Todos eram do sexo masculino, com média de idade 28,8 anos, hígidos que sofreram lesão durante a participação nesse torneio. O braço direito foi acometido em três pacientes (60%). O seguimento dos atletas foi, em média, de 4,6 meses, sendo que a queixa de dor estava presente em todos os casos. O exame clínico da região do cotovelo foi realizado imediatamente após a ocorrência da lesão e no momento da realização do exame de ressonância magnética (RM). O exame radiográfico não demonstrou alterações. Durante o exame clínico, foram detectados pontos dolorosos específicos na topografia medial e anterior dos cotovelos examinados, na qual não se observaram instabilidades ligamentares do cotovelo durante os testes dinâmicos. Resultados: Os principais achados da RM foram: lesão do tendão comum dos músculos flexores e do ligamento colateral ulnar, contusão óssea na porção distal do úmero e do olécrano e derrame articular. Conclusão: O principal padrão de lesão reconhecido pela RM nos atletas estudados foi a lesão do complexo medial do cotovelo. Sugerimos que o mecanismo primário que determinou as lesões foi a hiperextensão do cotovelo aplicada com a posição neutra do antebraço. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Cotovelo. Articulação do cotovelo. Luxações. Traumatismos em atletas.*

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INTRODUCTION

The elbow is one of the most stable joints in the locomotor apparatus. When the architecture of this segment is disrupted due to damage to one or more of the structures, especially when associated with dislocation, there is an exacerbated chance of recurring instability, which inevitably leads to early degenerative osteoarthritis.[1]

Isolated dislocation of the elbow is the second most common arm injury and is classified as simple or complex according to the presence of associated fractures; peak incidence occurs between 5 and 25 years of age.[1,2]

There is a clear perception of evolution in treatment for an unstable elbow, particularly in recent years. Studies published recently have demonstrated the anatomical and functional characteristics of the stabilizers of this structure, and have been reinforced by the insertion of the physiopathology of instability.[2]

The strength of the elbow is promoted by stabilizing structures where the ulnar-humeral joint, the anterior band of the medial collateral ligament (MCL), and the complex lateral ligament are the three main static elements. The periarticular muscle groups are dynamic contributors that promote an increase in constrictive force.[2,3]

According to O'Driscoll et al.,[4] most elbow dislocations result from falls where the hand is extended. Axial force applied in valgus associated with supination is the main determining factor for damage when this force is directly transmitted on the elbow. This combination of forces produces a sequential rupture across the soft tissues that begins in the region of the lateral collateral ligament (LCL). The same force progresses to the anterior and posterior capsule and finally dissipates to the MCL.[4] This sequence of damage determines varying levels of instability that range from partial to complete dislocation and may occasionally be associated with fractures.

The reports by Ring and Jupiter[5] called attention to the fact that the structures responsible for the stability of the elbow are arranged as a supporting ring containing anterior, posterior, medial, and lateral elements where the possibility of instability is proportional to the gravity of the injuries. In this way, these authors corroborated the concepts presented by other previous studies.

Treatment in these cases is preferably conservative. Immobilization with a cast followed by early active mobilization is recommended to resolve the high risk of joint stiffness with concomitant limitation of range of motion. When reduction of the dislocation is easily obtained with indisputable stability, some physicians prefer not to immobilize. However, detection of joint instability is considered a criterion for repair or reconstruction of the injured ligaments.[2,6,7]

We note that Jiu-Jitsu is gradually becoming more popular and that interest in understanding and treating injuries associated with this sport has grown among physicians who work in sports medicine. When we refer to the straight armbar (also known as *juji-gatame*), we note that this type of armlock is commonly and effectively applied in fighting sports; technically, it is applied to the hyperextended elbow with the forearm kept in a neutral position. There are very few reports in the literature on injuries and the mechanism of injury in this maneuver, which determines a specific pattern of injury. As a result, this injury has increased considerably as the popularity of this sport increases. Therefore, the primary objective of this study was to describe injuries resulting from application of the straight armbar-type armlock in high-yield Jiu-Jitsu athletes.

MATERIALS AND METHODS

Initially, this research project was submitted to the institutional review board, as determined by Resolution 196/96 of the National Health Council for research involving humans, and was approved for implementation under CAS protocol 645458.

The participants were informed of the objectives of the study in detail and all procedures to which they would be subjected. They agreed to participate in this study and subsequently signed the informed consent form.

We considered the following inclusion criteria healthy Jiu-Jitsu athletes without comorbidities, without prior injury, without previous treatment (clinical or surgical) who injured their elbows as a result of the armbar-type armlock.

During this maneuver, the opponent is trapped in dorsal decubitus position, and the attacked arm is maintained in a neutral position between the legs of the attacking fighter. Force is then applied with the hip to hyperextend the opponent's elbow, with the forearm maintained in neutral position. (Figure 1)

The exclusion criteria were age <18 years, cognitive or other deficit that might interfere with data collection and assessment.

Five Brazilian Jiu-Jitsu practitioners from the Gracie Elite gym who were injured as a result of the armbar-type armlock during a competition were included in the study. The injuries occurred between November 2014 and July 2015. All the patients were male, and mean age was 28.8 years. They had no comorbidities. The right elbow was affected in 60% of cases. Pain was present in 100% of cases, and the mean follow-up time averaged 4.6 months. (Table 1)

All the injuries were detected by the lead investigator of this study, who was also a member of the medical support staff for the tournament. This physician is also a regular practitioner of this martial art and witnessed the injuries at the exact moment when they occurred. All patients received a physical orthopedic examination in which clinical maneuvers were applied to evaluate instabilities and distinguish potentially injured structures immediately after the injury. Next, X-rays were taken of the elbows in the antero-posterior and lateral views.

The patients then underwent MR imaging, on average three days after the injury; four (80%) received MRI on the second day and one (20%) on the seventh day.

The X-ray and MR images were evaluated jointly with a team of radiologists (associated with the Brazilian College of Radiology and

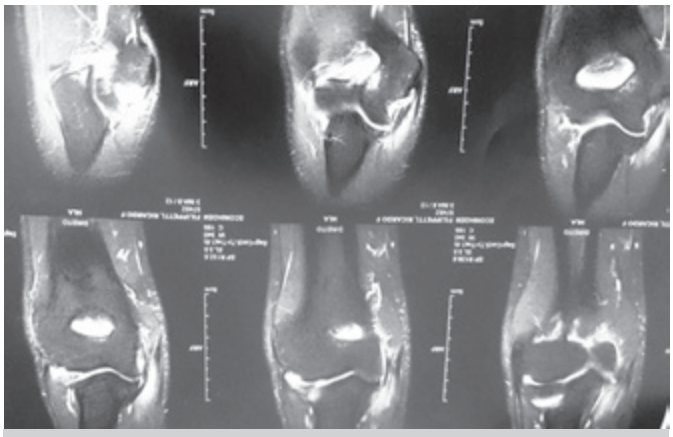

Figure 1. Injury to the medial complex of the elbow.

Table 1. Clinical data for the patients injured during armbar-type armlock of the elbow.

Patient	Age	Sex	Elbow affected	Time MRI
1	33 years	Male	Right	2 days
2	40 years	Male	Right	2 days
3	25 years	Male	Right	2 days
4	28 years	Male	Left	7 days
5	18 years	Male	Left	2 days

Diagnostic Imaging), a specialist in locomotor disorders, and three orthopedic physicians specializing in shoulder and elbow surgery (members of Brazilian Society of Orthopedics and Traumatology and the Brazilian Society for Shoulder and Elbow Surgery).

RESULTS

The initial clinical examination showed the following symptoms: pain in the region of the olecranon associated with diffuse pain, mainly in the medial region of the elbow and pain on palpation. Instability tests were negative.

X-rays of the elbow showed no changes. The MRIs in the five athletes who participated in the study showed total or partial rupture of the common flexor tendon. The ulnar collateral ligament was ruptured in 100% of the cases. (Figure 2)

We observed the presence of areas of contusion and microfractures of the bone marrow in the distal portion of the humerus and olecranon in 60% of cases. (Figure 3)

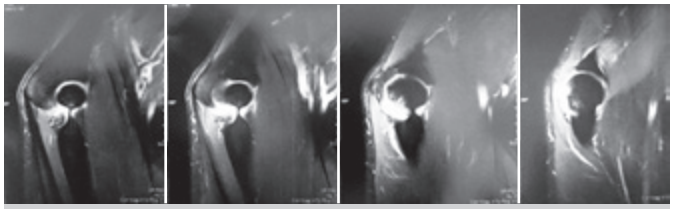

Figure 2. Edema of the olecranon.

Figure 3. Armbar-type armlock.

DISCUSSION

The armbar-type armlock is one of the maneuvers most frequently applied by martial arts athletes, especially Brazilian Jiu-Jitsu. In this armlock, the attacking fighter traps his opponent in dorsal decubitus, holding the defending athlete's arm in a neutral position between the attacking fighter's legs. Next, force is applied with the hip to hyperextend the opponent's elbow with the forearm in neutral rotation. We emphasize that this technique requires precise application to be effective. The defending athlete can extricate himself if he can change the position of his forearm, keeping it in a pronated or supinated position.

As for the mechanism of injury, we found no studies that biomechanically tested this fighting position. However, in the literature we found a study by An et al.,[8] who reported that this injury entails a pattern of damage determined by the action of the muscle on the static elbow with the forearm maintained in neutral rotation; these authors evaluated the mechanical effects of this segment in positions of flexion, extension, and semi-flexion. In all positions analyzed, these authors observed that the main stabilizer of the elbow is the extensor carpi radialis, but in semi-flexion there is also a collaboration of the flexor muscles.[8]

We therefore surmise that the likely pattern of injury is caused by an eccentric force of contraction by the forearm flexor muscles, thus generating injury to the dynamic and static medial stabilizers of the elbow, in agreement with the clinical and MRI findings in our study.

CONCLUSION

The armbar-type armlock results in an injury to the medial structures of the elbow that suffer progressively from an overload resulting in turn from a hyperextension mechanism in which the forearm is trapped in the neutral rotation position, according to the findings in our study.

We did not find similar studies in our search of the literature, indicating the originality of our publication. The active search for the injury pattern presented in accordance with the mechanism described above may assist in predicting and planning treatment in similar cases. However, there is a clear need to increase the study sample to enhance the consistency of the epidemiological findings.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. TBCA (0000-0002-5708-5450)*, AYN (0000-0002-6451-8488)*, and ETD (0000-0001-6735-1401)* were the main contributors in writing the manuscript. LP (0000-0001-9914-4327)*, EBAJ (0000-0002-9456-2869)*, LMRR (0000-0001-6891-5395)*, and TBCA, analyzed the images. TBCA, AYN, and EBAJ evaluated the data for the statistical analysis. ETD, LMRR, and LP conducted the bibliographic research, revised the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

PROSPECTIVE EVALUATION OF INJURIES OCURRED DURING A PROFESSIONAL SOCCER CHAMPIONSHIP IN 2016 IN SÃO PAULO, BRAZIL

AVALIAÇÃO PROSPECTIVA DAS LESÕES DURANTE O CAMPEONATO PAULISTA DE FUTEBOL DE 2016

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ABSTRACT

Objective: To identify the incidence of injuries, their main characteristics, and the way they were managed throughout 2016 in two major series of a professional soccer championship in São Paulo, Brazil. Methods: This prospective study used an electronic questionnaire previously developed by the Medical Committee of the Paulista Soccer Federation which was sent to the team doctors after each match. Results: Two hundred and fifty-nine injuries occurred during 361 matches, and the incidence of injury per 1000 hours of game play was 21.32. Strikers were the most affected by injury; the most frequent diagnosis was muscle injury and the legs were predominantly affected. Most of the injuries occurred in the last 15 minutes of the first half and only 7.7% required surgical treatment. Conclusions: Muscle injuries were the most frequent, with most occurring in forwards and in the legs. Approximately half of the injuries occurred after contact and the vast majority was treated without surgery. MRI was the most requested exam and most injuries were classified as moderate (8 to 28 lost play days). ***Level of Evidence III, Study of Non Consecutive Patients; Without Consistently Applied Reference "Gold" Standard.***

Keywords: Soccer. Athletes. Wounds and injuries. Epidemiology.

RESUMO

Objetivo: Identificar a incidência de lesões, suas principais características e a maneira como foram conduzidas durante todo o ano de 2016 nas duas principais séries (A1 e A2) do Campeonato Paulista. Métodos: Realizou-se um estudo prospectivo por meio de questionário eletrônico previamente desenvolvido pelo Comitê Médico da Federação Paulista de Futebol, que foi enviado aos médicos dos times das séries A1 e A2 do Campeonato Paulista de Futebol após cada rodada. Resultados: Houve 259 lesões durante 361 jogos, com incidência de 21,32 lesões por 1.000 horas de jogo ao se agrupar as duas séries do Campeonato Paulista. Os atacantes foram os mais envolvidos, sendo as lesões musculares as mais frequentes e os membros inferiores os mais afetados. A maioria das lesões ocorreu nos últimos 15 minutos do primeiro tempo e somente 7,7% das lesões precisaram de tratamento cirúrgico. Conclusões: As lesões musculares são as mais frequentes, sendo que a maioria ocorreu em atacantes e nos membros inferiores. Cerca de metade das lesões ocorreu após contato e a maioria absoluta das lesões foi tratada de forma não cirúrgica. A ressonância magnética foi o exame mais solicitado e a maior parte das lesões foi classificada como de gravidade moderada (8 a 28 dias de afastamento). ***Nível de Evidência III, Estudo de Pacientes Não-Consecutivos; Sem Padrão de Referência "Ouro" Aplicado Uniformente.***

Descritores: *Futebol. Atletas. Ferimentos e lesões. Epidemiologia.*

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INTRODUCTION

Soccer is the most popular sport in the world, with an estimated 240 million amateur athletes and at least 200,000 professional athletes. It is a sport that covers all age ranges, both sexes, and presents a high rate of injuries (70 injuries per 1000 hours of play).[1] Soccer features short, fast, and non-continuous movements like acceleration, deceleration, changes in direction and leaps, and also involves extensive contact, which leads to injuries.[2,3]
National entities from countries as USA and UEFA tend to characterize and disclose injuries from their major championships in order to develop programs to prevent and reduce morbidity caused by soccer-related injuries. Previous studies have reported

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that muscle injuries, contusions, and sprains comprise 75% of injuries in professional soccer players, with the majority affecting i the legs (60-85%).[4]

Brazil has a large number of practitioners and is considered to have some of the best players in the world. The data are sparse and little is known about types of injuries and how and when they occur, which makes it difficult to prevent and treat these injuries and to rehabilitate the players.[5]

The objective of this study was to identify the incidence of injuries, their main features, and how they were handled throughout 2016 during the two main series (A1 and A2) of the Campeonato Paulista (São Paulo State Championship).

MATERIALS AND METHODS

This research project was approved by the institutional review board (number 56723616.3.0000.5505).

This prospective study was conducted using an electronic questionnaire previously developed by the Medical Committee of the Paulista Soccer Federation and sent to the physicians for the teams in series A1 and A2 after each round of the 2016 São Paulo State Championship. All participants signed the Informed Consent Form prior to participating in the study.

A questionnaire was sent after each round to assess the incidence of injuries and their characteristics. The questionnaire consisted of 10 questions about the characteristics of the game, the athlete, and of the injury. (Annex 1)

The concept used to define soccer injuries was the same chosen by Fuller et al.[6] for the 2005 FIFA consensus, describing them as: "Any physical complaint sustained by a player that results from a football match or football training, irrespective of the need for medical attention or time loss from football activities."

To evaluate the outcome of the injuries reported, a questionnaire was sent for each injury which occurred and was completed after the athlete returned to training and game play. The questionnaire was comprised of six questions spanning from the complementary examination performed to the final diagnosis. (Annex 2)

To obtain the game schedules, we requested the game records from the Paulista Soccer Federation and divided the schedules as follows: morning (start before noon), afternoon (start before 6 p.m.), and night (start after 6 p.m.).

To assess the risk of injury we calculated the incidence of injury, which is expressed by the number of injuries per 1000 hours of exposure.[6,7] To calculate exposure in games we used the following formula:

Exposure = number of injuries in games x number of players participating in the game x game duration in minutes / 60'

To calculate the incidence in games we used the following formula:

Incidence = number of injuries in games x 1000 hours/time of exposure

Statistical analysis

We used statistical tests because the data were quantitative and continuous. We used the equality of two proportions test to characterize the distribution of the relative frequency of the qualitative variables. Differences with $p<0.05$ were considered statistically significant. SPSS V17 software was used to conduct the analysis.

RESULTS

The mean age of the injured players was 26.8 years, and the mean number of days lost as a result of injuries was 23.2. The fewest games took place in the morning (11.2%), 34.1% of the games took place in the afternoon, and 54.7% took place at night.

During a total of 361 games 259 injuries were described, with an average of 0.71 injuries per game. Of the total, 27% of the injuries occurred in strikers, 17.4% in attacking midfielders, 17.4% in defensive midfielders, 17% in full-backs, 15.8% in central-backs, and 5.4% in goalkeepers. Most injuries occurred at the end of the first half, between the 31- and 45-minute mark (25.1%). (Figure 1)

As for location, the most frequent injuries were to the legs (73.4%), head (15.1%), arms (6.2%), and trunk (5.4%). The right side was most frequently affected (45.6%) and 17.8% of injuries were not classifiable as one side or the other. Contact was involved in 49% of the injuries.

As for type of injury, muscle strains were the most common (39.8%), followed by sprains (20.5%) and contusions (16.6%). (Figure 2)

The most common initial diagnoses were hamstring muscle injury (23.9%), adductor muscle injury (7.7%), injury to the lateral ligament of the ankle (5.8%), quadriceps muscle injury (5%), concussion (3.9%), and facial cut/contusion (3.9%).

During series A1, there were 24.16 injuries per 1000 hours of play, and in series A2 there were 19.10 injuries per 1000 hours of play. For the two series combined, there were 21.32 injuries per 1000 hours of game play.

When requested, the most common complementary exams performed were magnetic resonance imaging (36.7%) and ultrasound (28.2%), followed by X-rays (15.4%) and computed tomography (6.6%). Only 7.7% of the injuries required surgery. The most common injuries (34.4%) were considered moderate according to the severity scale, with lost time of 8 to 28 days. (Figure 3)

DISCUSSION

The mean number of days the athletes lost per injury was 23.2. There was an incidence of 21.32 injuries per 1000 hours of game play for

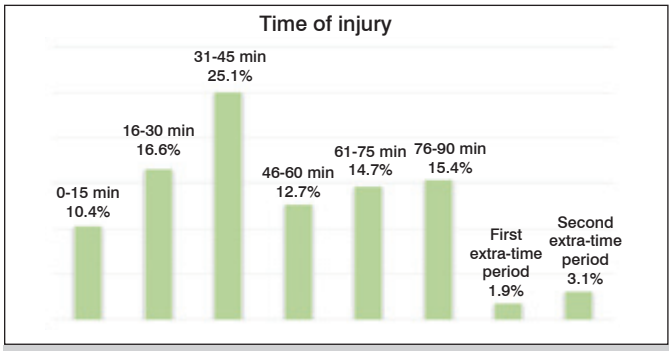

Figure 1. Time of injury.

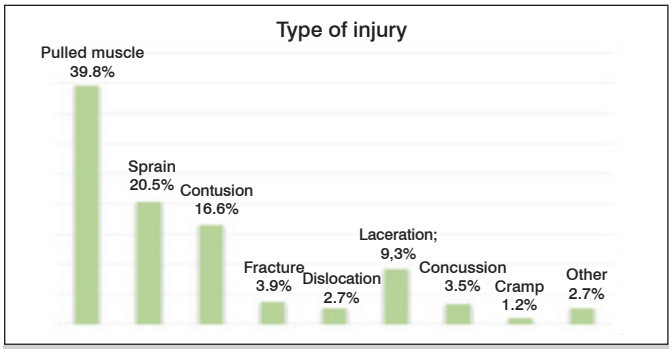

Figure 2. Type of injury.

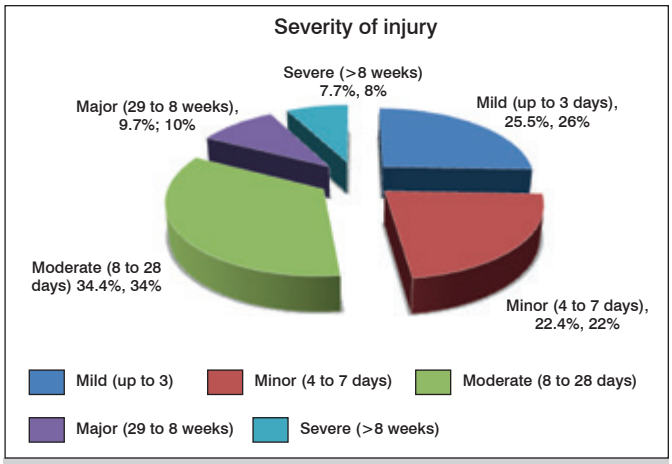

Figure 3. Severity of injuries.

both series of the São Paulo State Championship soccer championship combined. Most injuries occurred during the last 15 minutes of the first half and only 7.7% of the injuries required surgical treatment.

A number of studies have investigated the incidence and main causes of soccer injuries.[1,7-11] The mean age of the injured players in this present study was 26.8 years, higher than described in the literature.[5,12] On average, athletes lost 23.2 days of play after injury, more than indicated in the study by Stubbe et al.,[13] who found an average of 8 days of lost play. One possible explanation for this high average was the presence of 10 cases of tears in the anterior cruciate ligament of the knee, which led to an average of more than 6 months of lost play. We found an average of 0.71 injuries per game, below the number found in several studies in the literature including Pedrinelli et al.[1] and Junge and Dvorak,[14] who found 2.4 injuries per game. This difference may be because our study assessed more players than the other studies.

As for prevalence according to the diagnosis, contusions, muscle strains and sprains are the most frequent injuries in the literature, most commonly in the legs.[1,15-18] Our study shows similar results; not only were leg injuries the absolute majority (73.4%), but muscle strains and sprains were most common. Strikers were the most affected by injuries; this finding counters the results of previous studies in which midfielders were most affected.[19,20] This may be because these studies did not divide midfield players into defensive and attacking midfielders as we did in this present study. As for the incidence of injuries per 1000 hours of play, we found results that are within the range found in the literature, from 15 to 70 injuries per 1000 hours of game play.[1,21-23] It should be noted that the values vary so widely in previous studies because of differences in study design, data collection methods, and the definition of injury.[24] Our study also differed from the literature in terms of the time of injury, which was more common between the 31 and 45 minute mark, while other studies have shown that most injuries occurred in the last 30 minutes of the game.[1,22] In our study, 49% of the injuries occurred after contact, results which are similar to the findings by Pedrinelli et al.,[1] but less than the literature in which more than 70% of injuries occur after contact.[22,23]

The most commonly requested supplementary examination after injury was magnetic resonance imaging; this may result from the fact that muscle injuries were most common, and these types of injuries are generally assessed via this examination. In our study, most injuries were considered moderate (8 to 28 days of lost play), which is similar to the findings by Stubbe et al.[13] but differs from Pedrinelli et al.[1] and Cohen et al.,[12] who found mild injuries (4 to 7 days lost) to be most common. Only 7.7% of the injuries required surgery, which results from the fact that the vast majority of injuries which affect soccer players (such as muscle strains and contusions) are managed conservatively.

This study has some methodological limitations. There is the possibility of outcome information bias, since precise data on the injuries may have been altered or even omitted by the team physicians. Furthermore, the study evaluated acute injuries which occurred during games, and consequently chronic injuries as well as those which occurred during practice and diseases unrelated to sports were not recorded. In a study conducted during the 2010 World Cup by Dvorak et al.,[25] injuries that occurred during practice had very different diagnoses than those which occurred during the game play, but the severity of the injuries was similar and non-sports diseases affected approximately 12% of the players. We believe it is important to expand medical supervision for injuries during practice and off-field diseases in the players. Another point was that exposure time was calculated using 22 players and 90 minutes of play. A more precise method would be to consider extra time or the real time for each game and the number of minutes of exposure for each individual player.

The information in this study is critical to preventing new injuries in soccer. The data will allow athletes and medical staff in clubs and federations to carry out preventative programs aiming at reducing the incidence of injuries in the sport.

CONCLUSIONS

Muscle injuries were the most frequent, with most injuries affecting strikers and the legs. Approximately half of the injuries occurred after contact and most were treated non-surgically. Magnetic resonance imaging was the most frequently requested exam and most of the injuries were classified as moderate (with 8 to 28 days lost).

ACKNOWLEDGMENTS

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Annex 1. Injury mapping questionnaire.

Mapping of Injuries from the 2016 Campeonato Paulista (São Paulo Professional Soccer Championship)

1. What game are you reporting below?
_____

2. Were there injuries in this game?
( ) Yes ( ) No

3. What is the athlete's date of birth?
___/___/___

4. What is the athlete's position?
( ) Goalkeeper ( ) Outside back
( ) Central defender ( ) Defensive midfielder
( ) Midfielder ( ) Forward

5. When did the injury occur?
( ) 0-15 min. ( ) 16-30 min.
( ) 31-45 min. ( ) 46-60 min.
( ) 61-75 min. ( ) 76-90 min.
( ) Extra time, first half ( ) Extra time, second half

6. Area of body where injury occurred:
( ) Head ( ) Trunk
( ) Arm ( ) Leg

7. Side of injury:
( ) Right ( ) Left ( ) Not applicable

8. Type of injury
( ) Pulled muscle ( ) Sprain ( ) Contusion
( ) Fracture ( ) Dislocation ( ) Cut-contusion trauma
( ) Concussion ( ) Cramp ( ) Others

9. Did the injury occur after contact or collision with the ball, the goalposts, or other athlete?
( ) Yes ( ) No

10. Initial diagnosis (likely)
_____

Annex 2. Injury follow-up questionnaire.

Follow-up of Injuries from the 2016 Campeonato Paulista (São Paulo Professional Soccer Championship)

1. What complementary examinations were requested?
( ) None ( ) X-ray ( ) US ( ) CT
( ) MRI ( ) Other (please specify) _____

2. Did the injury require surgery?
( ) Yes ( ) No ( ) If so, what?_____

3. Days lost:_____

4. Injury Severity Scale:
( ) Mild (up to 3 days lost) ( ) Minor (up to 7 days lost)
( ) Moderate (8 to 28 days lost) ( ) Major (29 days to 8 weeks lost)
( ) Severe (>8 weeks lost)

5. Final diagnosis:_____

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ORIGINAL ARTICLE

ORTHOPEDIC INJURIES IN SOCCER – AN ANALYSIS OF A PROFESSIONAL CHAMPIONSHIP TOURNAMENT IN BRAZIL

LESÕES ORTOPÉDICAS NO FUTEBOL – ANÁLISE DO CAMPEONATO PAULISTA DA SÉRIE A2

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ABSTRACT

Objective: To analyze the incidence of orthopedic injuries which occurred during a professional soccer championship in São Paulo, Brazil in 2010. Methods: This assessment collected data from the pre-season until the final stage of the championship. Results: We analyzed 227 professional players from eight of the top teams in this championship. Data were obtained for 71.02% of all games. The athletes were all male with a mean age of 23.1 years; the average number of injuries was 1.6 per athlete, with muscle injuries and sprains resulting from indirect origin predominating in the legs. Conclusion: Injuries were more frequent in forwards and outside backs, and players generally returned to play within one week of treatment. ***Level of Evidence III, Study of Non Consecutive Patients; Without Consistently Applied Reference "Gold" Standard.***

Keywords: Soccer. Athletic injuries. Wounds and injuries.

RESUMO

Objetivo: Analisar a incidência de lesões ortopédicas ocorridas durante o Campeonato Paulista Profissional da Série A2 de 2010. Métodos: Esta avaliação restringiu-se à coleta de dados desde a pré-temporada até a fase final do campeonato. Resultados: Foram analisados 227 jogadores profissionais de oito das principais equipes deste campeonato. Foram obtidos dados de 71,02% do total de jogos. Os atletas eram todos do sexo masculino, com média de idade de 23,1 anos; o número médio de lesões foi de 1,6 por atleta com predomínio de lesões musculares e entorses indiretos nos membros inferiores. Conclusão: Houve uma frequência maior de lesão em atacantes e laterais, com retorno predominante ao esporte em até uma semana de tratamento. ***Nível de Evidência III, Estudo de Pacientes Não Consecutivos; Sem Padrão de Referência "Ouro" Aplicado Uniformemente.***

Descritores: *Futebol. Traumatismos em atletas. Ferimentos e lesões.*

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INTRODUCTION

Competitive sports became more popular during the nineteenth century, beginning with the Modern Olympic Games in Athens and Greece in 1896. The populations of many countries were encouraged to exhibit their sports performances and seek superiority. Many sports were created and developed, and some reached great popularity; most notable among these is soccer, which is among the most popular sports practiced by both sexes in different age groups. FIFA, the International Football Federation, currently contains 203 member countries and approximately 200 million players.[1]

In Brazil, the history of soccer begins with Charles Miller, who was born in the Brás neighborhood of São Paulo. When he was nine years old, he went to England to study and came into contact with soccer; when he returned to Brazil in 1894 he brought the first soccer ball and a set of rules. Brazil's first soccer game took place on April 15, 1895 between employees of British companies which were present in São Paulo. The first team to form in Brazil was São Paulo Athletic, founded on May 12, 1888. Initially, only the elites played soccer, and Blacks were even banned from teams, but over time drastic changes took place in the sport, mainly due to professionalism and the increasing physical demands which forced athletes to work to near-exhaustion and caused them to be more predisposed to injuries.[2]

In our environment, it has been difficult to achieve a balance between preparation and athletic demands. Advances in sports medicine have led us to a better understanding of the physiology of effort, allowing specific protocols for each athlete and individualizing their characteristic; on the other hand, the large number of games, trainings, and the broad availability of athletes, places them at risk for injuries to muscles, bones, and joints.[3]

Athletes are considered to be models of health because of their optimal physical capacity, and therefore have trouble accepting the need to trade the soccer field for the medical department.[3] In some situations, like injuries in professional athletes, physicians

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should be fully aware of their own behavior, because in soccer there is constant pressure to keep players on the field or to return players to action as early as possible.

Historically, in 1952 Naves[4] was the first to report a relationship between soccer and traumatic injuries over 4,000 games and 10 years. In 1978, McMaster and Walter[5] performed the first prospective study of soccer injuries in the American literature. Also in 1978, Nilsson and Roaas[6] studied two Norwegian championships and found that 56% of injuries occurred during the period of the game, two-thirds of these affected the legs, and that contusions were the most common injuries. In 1989, Ekstrand and Nigg[7] associated soccer injuries with the use of inadequate footwear as well as the type of grass or soil used.

In the Brazilian literature, in 1992 Carazzato et al.[8] studied and compared field and indoor soccer injuries according to diagnosis and anatomic location of injuries. And in 1994, Pedrinelli[9] surveyed 354 traumatic injuries in 150 professional soccer players, highlighting age, injury location, the athlete's position on the field, and etiology. This researcher concluded that the most frequent injuries occurred in the legs, without contact.

There are many variables related to injuries in soccer, so we divided these variables into two groups: 1) intrinsic - those which are inherent to the sport itself, such as short and fast runs, leaps, quick changes in direction, heading the ball, etc.; and 2) extrinsic - which evaluate the field conditions, type of footwear, physical conditions and health, sex, number of games, training, and motivation.

Considering the characteristics of soccer, the objective of this study was to analyze the incidence of orthopedic injuries which occurred during the A2 series of the 2010 Campeonato Paulista Profissional (São Paulo Professional Championship).

MATERIALS AND METHODS

In this study, we analyzed the medical records of 227 professional players from 8 of the top teams of the A2 series of the 2010 Campeonato Paulista professional soccer championship. This assessment was restricted to data collected from the pre-season until the final stage of the championship.

The inclusion criterion was professional soccer players who competed in the A2 series of the 2010 Campeonato Paulista. The exclusion criterion was loss to follow-up of athletes after leaving the club or the sport or for some other reason that did not permit us to analyze the time it took to return to the sport.

The variables used in this study were: number of players available for the competition, total number of games, age, position played, mechanism of injury, anatomical location of the injury, type of injury, temporality of the injury (pre-season, training, or game), treatment established, time lost from play, and conditions to return to the sport.

The injuries were assessed according to each player's position on the field, namely goalkeeper, outside back (*lateral*), central defender (*zagueiro*), midfielder, center forward (*centroavante*), and right/left forwards (*ponta*).

The diagnoses were made by the team physicians and divided into contusions, fractures and dislocations, ligament injuries, muscle injuries, and tendonitis. Complementary exams were used for follow-up, such as chest x-rays, ultrasound, and magnetic resonance imaging.

Injury locations were classified by segments: trunk (head and neck, dorsal spine and thorax, lumbar spine and pelvic girdle), legs (thigh, knee, leg, ankle, and foot), and arms (shoulder, arm, elbow, forearm, wrist, and hand).

The injuries were classified according to the mechanism of occurrence, direct contact and non-contact.

The period of time lost was considered to span the time of injury until release to participate in team practice, and used to classify the injuries as mild (0-7 days), moderate (8-30 days), or severe (> 31 days).

The data were obtained from the athletes' medical records, which in turn were obtained from their teams. These variables were recorded on spreadsheets which were computed and analyzed by the authors of this study.

The championship competition, which included 20 participating teams, ran from January 13 to May 2, 2010 and was conducted in two stages in which each team played at least 19 and at most 25 games. During the first stage, the 20 teams played against each other once in order to classify for the second stage, in which the 8 teams with the highest point scores played. These 8 teams were divided into two groups of 4 which played among their respective groups in a match and rematch.

The pre-season period, which immediately precedes the championship, lasted an average of 30 days and required the medical department professionals to dedicate more time to their team for planning and implementing specific tasks for the start of the season. As many athletes return from vacations or downtime, the rigor of the beginning of the season implies demands on the musculoskeletal system that can generate injuries from overload. The pre-season allows physicians and physiotherapists to see which athletes will require preventive care during the season to withstand their game calendar, which generally is intense and irregular.

Foot injuries such as blisters and calluses are frequent and less severe, and may even harm performance in team practice and physical training sessions, but these were not analyzed due to their lack of correlation with orthopedic injuries.

The average practice time followed a theoretical standard composed of 10 to 14 training periods per week (two three-hour training periods per day); twice a week, before and after games, the athletes were gathered but did not perform physical activities. Changes were made when necessary according to team needs.

RESULTS

The championship had a total of 214 games and 7,436 fouls, averaging 34.0 fouls per game: 1,265 yellow cards, an average of 5.0 per game, and 141 red cards with an average of 0.65 per game. (Table 1)

Of the 227 medical records, a total of 42 athletes were excluded from our sample. Data were obtained from 152 of the 214 games during this championship, for a total of 71.02%, but data were analyzed for 40%, for 8 of the 20 participating teams. Each team had between 26 and 38 players available, with an average of 28.4 athletes per team. Player ages ranged from 17 to 42 years, with a mean of 23.1.

The average number of orthopedic injuries per athlete was 1.6 in 4 months. Figure 1 shows the types of injuries sustained by the athletes, with a predominance of muscle injuries and sprains.

As for anatomic location, 85.3% (n = 309) involved the legs, 7.8% (n = 28) were in the trunk, and 6.9% (n = 25) the arms. (Figure 2)

The vast majority of injuries were diagnosed clinically. Only in the more serious cases in which doubt was present were the athletes were subjected to complementary examinations. The average time lost as a result of injury varied markedly according to injury type, as can be seen in Figure 3, but in some cases the player was lost to follow-up after injury.

Figure 4 shows the average number of injuries according to the position of the athlete. In our sample, the forward players and outside backs had the most injuries during the season.

We found 43.1% of injuries resulted from direct contact and 56.9% involved no contact. (Figure 5) Of the non-contact injuries, 62.1% were muscle injuries, while 38.9% of injuries from direct contact were contusions.

Table 1. General data per round of the A2 series of the Campeonato Paulista professional football championship.

	Games		Fouls		Goals		Yellow Cards		Red Cards		Game Play	
	Games	Total	Fouls	Mean	Goals	Mean	Yellow	Mean	Red	Mean	Time	Mean
Round 01	1 0	10	345	34.00	25	200	52	5.00	2	0.00	10:03:27	01:00:20
Round 02	10	20	409	40.00	23	200	55	5.00	5	0.00	09:55:21	00:59:32
Round 03	10	30	355	35.00	14	1.00	60	6.00	5	0.00	10:15:04	01:01:30
Round 04	10	40	380	38.00	35	3.00	54	5.00	5	0.00	10:08:08	01:00:48
Round 05	10	50	370	37.00	31	3.00	71	7.00	9	0.00	09:58:08	00:59:48
Round 06	10	60	312	31.00	33	3.00	61	6.00	3	0.00	10:10:46	01:01:04
Round 07	10	70	377	37.00	33	3.00	64	6.00	3	0.00	10:16:00	01:01:36
Round 08	10	80	310	31.00	20	2.00	69	6.00	10	1.00	09:56:26	00:59:38
Round 09	10	90	338	33.00	27	2.00	45	4.00	2	0.00	10:10:55	01:01:05
Round 10	10	100	346	34.00	39	3.00	59	5.00	8	0.00	10:12:06	01:01:12
Round 11	10	110	318	31.00	31	3.00	50	500	6	0.00	10:10:29	01:01:02
Round 12	10	120	364	36.00	31	3.00	68	6.00	12	1.00	09:55:44	00:59:34
Round 13	10	130	342	34.00	30	3.00	56	5.00	7	0.00	09:58:00	00:59:48
Round 14	10	140	368	36.00	28	2.00	58	5.00	12	1.00	09:58:30	00:59:51
Round 15	10	150	350	35.00	39	3.00	57	5.00	5	0.00	10:23:45	01:02:22
Round 16	10	180	332	33.00	35	3.00	65	6.00	11	1.00	10:14:45	01:01:28
Round 17	10	170	294	29.00	29	2.00	43	4.00	5	0.00	09:53:06	00:59:18
Round 18	10	180	359	35.00	33	3.00	83	8.00	6	0.00	10:09:29	01:00:56
Round 19	10	190	309	30.00	34	3.00	53	5.00	8	0.00	10:05:41	01:00:34
Round 20	4	194	135	33.00	11	2.00	21	5.00	4	1.00	03:58:40	00:59:40
Round 21	4	198	165	41.00	12	3.00	21	5.00	5	1.00	04:09:25	01:02:21
Round 22	4	202	142	35.00	8	1.00	24	6.00	1	0.00	04:03:00	01:00:45
Round 23	4	206	158	39.00	14	3.00	28	7.00	3	0.00	04:08:45	01:02:11
Round 24	4	210	133	33.00	12	3.00	25	6.00	1	0.00	03:59:59	00:59:59
Round 25	4	214	125	31.00	19	4.00	23	5.00	3	0.00	04:07:00	01:01:45
Championship total		214	7.438	34.00	644	3.00	1.265	5.00	141	0.00	16:22:39	01:00:39

Source: Paulista Soccer Federation.

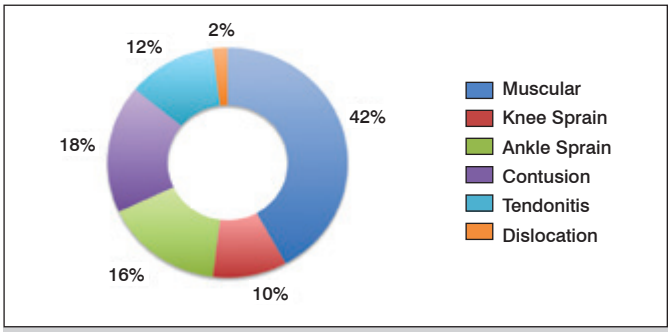

Figure 1. Types of injuries presented per athlete.

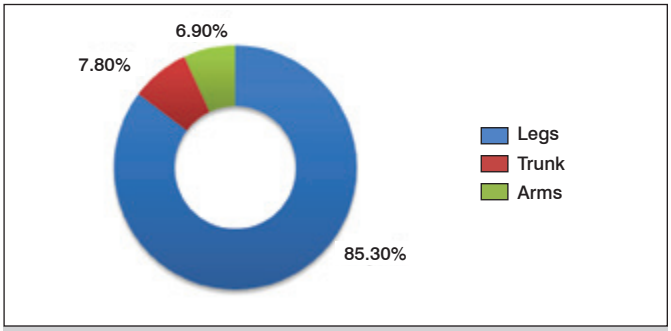

Figure 2. Anatomic location of injuries.

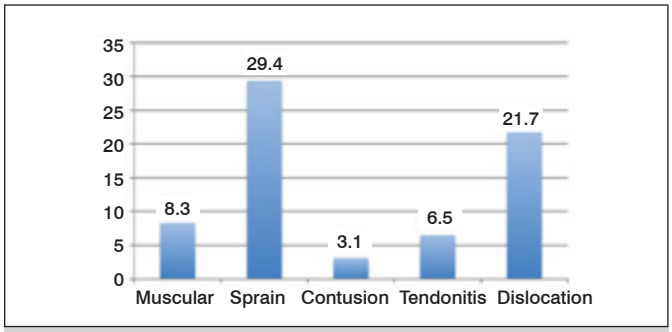

Figure 3. Average time before returning to play, in days.

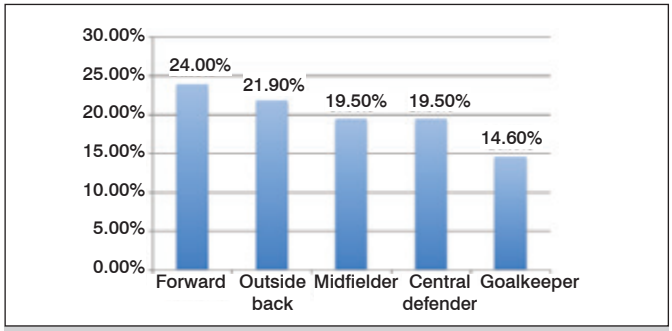

Figure 4. Average number of injuries according to position.

DISCUSSION

The analysis of the number of injuries according to player position showed a lower incidence in goalkeepers. When comparing defensive and offensive players, we observed a clear predominance of injuries in forwards and outside backs according to numbers alone; however, we must bear in mind the total number of athletes available for each position and the degree of trauma exposure to which each athlete is subjected.

As for frequency of injury diagnoses, our sample presented data compatible with those in the national literature by Ejnisman and Cohen[1] with a greater number of muscle injuries, but conflicted with the sample studied by Nilsson and Roaas,[6] who found a higher incidence of contusions.

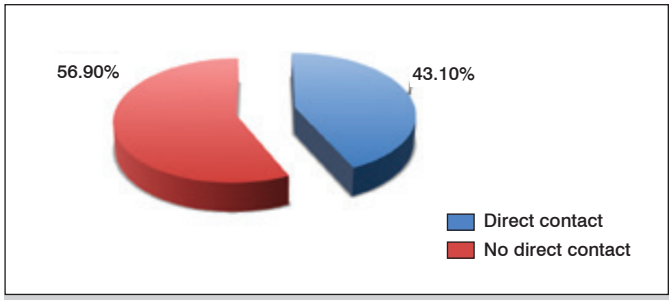

Figure 5. Mechanism of injury.

We must bear in mind that many athletes ignore their injuries, self-medicate, and seek guidance from professionals who are unrelated to their team medical department for fear that they will be benched, or as a result of lack of knowledge or greater confidence in another professional.

The lost time was greater for dislocations and fractures than other types of injury. The vast majority of contusions and sprains did not prevent the athletes from returning to football after more than a week, despite their high prevalence. Time lost to play did not follow a homogeneous pattern; some athletes relapsed when they returned to the game.

Because of the highly competitive of this soccer league, in our sample some players were lost to follow-up after injuries, transfers, being released from the team, or leaving the sport, among other situations. This occurred in most of the teams analyzed, which prevented us from accurately ascertaining physical response after returning to professional play. In some cases, the team was completely restructured due to their position in the rankings and hired new players during the championship, causing an information bias due to the total time the athlete was followed.

We found no studies in the literature with results comparable to those presented herein.

This is an observational, cross-sectional study containing information that reflects the specific analysis of this tournament. Other studies should be conducted to compare athletes in other championships, in several categories, to confirm possible differences in the results.

Consequently, efforts should be made in the area of physical preparation as well as the medical area so that mechanisms of injury prevention can be successfully implemented in professional soccer.

CONCLUSION

Based on the data from this study, we concluded that the frequency of injuries in professional athletes in football in a season was extremely high, since 61% of the athletes had some kind of injury during a season. The forward players and outside backs are most affected by injuries, predominantly via indirect trauma; muscle injuries were the most prevalent and legs were the most affected area of the body.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. RFRS (0000-0002-4394-7750)*, SM (0000-0002-6557-1272)* EMZ (0000-0003-2504-2680)*, and AYN (0000-0002-6451-8488)* drafted the manuscript. RFRS and FFRS (0000-0002-2040-1392)* collected the data. RFRS, EMZ, AYN, and ETD (0000-0001-6735-1401)* evaluated the data from the statistical analysis. RFRS, SM, FFRS, EMZ, AYN, and ETD carried out the bibliographic research, reviewed the manuscript, and contributed to the intellectual concept of the study. *ORCID (Open Researcher and Contributor ID).

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ORIGINAL ARTICLE

COMPLICATIONS AND MIDTERM OUTCOMES OF HEMIARTHROPLASTY IN HEMODIALYSIS PATIENTS

COMPLICAÇÕES E RESULTADOS A MÉDIO PRAZO DA HEMIARTROPLASTIA EM PACIENTES DE HEMODIÁLISE

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ABSTRACT

Objective: The aim of this study was to evaluate the functional results, complications, and morbidity and mortality rates in patients with end-stage chronic renal failure (ESCRF) with collum femoris fractures who were treated with hemiarthroplasty. Methods: From 2005 to 2013, patients with ESCRF admitted to our hospital with collum femoris fracture and treated with hemiarthroplasty were retrospectively evaluated, and 44 hips in 42 patients were included in the study. Duration of hospital stay, bleeding, complications, morbidity and mortality were recorded for each patient. At the last control evaluation, patients were assessed via pelvis x-ray and functional status according to Harris Hip Score (HHS). Results: Patients required a mean 2.7 units of erythrocyte suspension. Mean hospital stay was 19.74 days. The most common complication was bleeding. The complication rate was 38.1%; mortality rate at first-year follow-up was 42.8%, and mean HHS was 74.5. Conclusion: Collum femoris fractures are more common in ESCRF patients due to metabolic bone disease, and these patients had many comorbidities which may exacerbate high complication and mortality rates. Orthopedic surgeons should consider these higher complication rates and inform patients about the consequences of this treatment. ***Level of Evidence IV, Case Series.***

Keywords: Femoral neck fractures/complications. Kidney failure, chronic/complications. Hemiarthroplasty. Hemodialysis. Mortality.

RESUMO

Objetivo: O objetivo deste estudo foi avaliar os resultados funcionais, as complicações e as taxas de morbidade e mortalidade em pacientes com insuficiência renal crônica em estágio terminal (IRCT) com fraturas do colo do fêmur tratados com hemiartroplastia. Métodos: De 2005 a 2013, pacientes com IRCT internados em nosso hospital com fratura do colo do fêmur e tratados com hemiartroplastia foram avaliados retrospectivamente, e 44 quadris em 42 pacientes foram incluídos no estudo. Durante a estadia hospitalar, hemorragia, complicações, morbidade e mortalidade foram registradas para cada paciente. Na última avaliação de controle, os pacientes foram examinados com radiografias da pelve e quanto ao estado funcional, de acordo com o Harris Hip Score (HHS). Resultados: Os pacientes precisaram em média 2,7 unidades de suspensão de eritrócitos. A estadia hospitalar média foi 19,74 dias. A complicação mais comum foi hemorragia. A taxa de complicações foi 38,1%; a taxa de mortalidade no primeiro ano de acompanhamento foi 42,8% e o HHS médio foi 74,5. Conclusão: As fraturas de colo do fêmur são mais comuns em pacientes com IRCT, em decorrência da doença óssea metabólica, e esses pacientes apresentam muitas comorbidades que podem exacerbar as altas taxas de complicação e mortalidade. Os cirurgiões ortopédicos precisam considerar esses altos índices de complicações e informar os pacientes sobre as consequências desse tratamento. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Fraturas do colo femoral/complicações. Falência renal crônica/complicações. Hemiartroplastia. Hemodiálise. Mortalidade.*

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INTRODUCTION

Patients with end-stage renal failure have metabolic bone disease related to hemodialysis and comorbidities with renal failure such as low albumin levels, changes in calcium and phosphate levels, and high parathyroid hormone levels.[1-3] In hemodialysis patients, this metabolic bone disease brings with it 4 to 5 times the risk of fatigue or traumatic fractures, particularly collum femoris fractures.[1,3,4] In addition to the high risk of the collum femoris fractures in this group of patients, this metabolic disease causes problems in osteosynthesis of these fractures due to lower bone mineral density (BMD).[3-7] Therefore, in treating collum femoris fractures many authors have cited arthroplasty due to the high risk of failed osteosynthesis, non-union, avascular necrosis, and the need for revision surgery.[5-7]

On the other hand, these are high-risk patients for surgical procedures related to comorbidities such as diabetes mellitus, coronary

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artery disease, and peripheral arterial diseases.[8,9] Although arthroplasty seems the most sensible treatment option for problematic patients, the rates of complication, prosthesis survival, morbidity, and mortality for these patients are not well known because the literature on these topics is limited.[6,7]

The aim of this study was to evaluate the early and midterm functional results and rates of complications, prosthesis survival, morbidity, and mortality in patients with chronic renal failure who had collum femoris fractures and were treated with hemiarthroplasty.

MATERIALS AND METHODS

This retrospective study included 44 hips in 42 patients with chronic renal failure admitted to our clinic for collum femoris fractures and treated with hemiarthroplasty between 2005 and 2013. The surgical reports were retrieved from a computerized database, and three surgeons reviewed the patient charts for exclusion and inclusion criteria.

Mean patient age was 63.5 years (range: 49–95 years, standard deviation: 9.47) with mean follow-up of 52.3 months (range: 6–192, standard deviation: 19.63). Patients who underwent revision arthroplasty due to failed osteosynthesis, non-union, and avascular necrosis were excluded. Furthermore, all the patients included in the study underwent dialysis to treat end-stage renal failure.

Duration of hospital stay, postoperative bleeding, complications, morbidities, and mortality for the patients were recorded in the hospital's computerized database and in each patient's medical records. Two surgeons made a final control evaluation of the surviving patients and their functional status using the Harris hip score (HHS); patients were evaluated for prosthesis survival via anteroposterior (AP) pelvic x-ray and AP and lateral x-rays of the operated hip.

Detailed information on the surgical interventions was provided to all patients, and all patients signed an informed consent form for the surgical technique performed. This study was approved by the institutional review board (2014/1340).

Surgical technique

The posterior approach was used in all surgeries, which were performed by four surgeons. Patients were placed in lateral decubitus position. After the fractured head was exposed and removed, the femoral neck was reshaped and the appropriate polished, cemented femoral stem (Spectron, Smith & Nephew) was inserted. An appropriately-sized unipolar or bipolar head was implanted, and then reduction and stability control were performed. Posterior soft tissues were then repaired, and the fascia, subcutaneous tissue, and skin were closed following normal procedure.

After admittance, all patients received antiembolic socks and low-molecular-weight heparin (4000 anti-Xa IU/0.4 ml) as prophylaxis against deep-vein thrombosis. All patients were seen by nephrology specialists, and surgery was performed according to suggestions from these specialists. All patients received hemodialysis prior to the day of surgery and preoperative values for potassium and creatinine were closely monitored. All patients received prophylactic antibiotic therapy (first-generation cephalosporin 3 mg/kg) before surgery, which was maintained until the second day after the procedure.

Postoperative rehabilitation was planned according each individual patient. Patients walked with the aid of a walker the first day after the procedure if their general condition permitted this activity. Mobilization was postponed for patients requiring intensive care unit maintenance after surgery until they were admitted to the orthopedic service. Sutures were removed on the 15th day post-procedure and patients were followed at intervals of 6 weeks, 3 months, 6 months, and 1 year after surgery.

Statistical analysis

SPSS for Windows v12.0 software (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. In quantitative comparisons, data were assessed using Student's t-test and paired sample t-tests. For qualitative comparisons, data were assessed using the chi-square and Fisher's exact chi-square tests. Statistical significance was accepted at a 95% confidence interval and for p-values less than 0.05.

RESULTS

The mean age of the 42 patients (44 hips) was 63.5 years (range: 49–95 years, standard deviation: 9.47) with mean follow-up of 52.3 months (range: 6–192, standard deviation: 19.63). Twenty-nine patients were female and 13 were male. (p=0.083) The left hip was affected in 24 patients, and the right in 20 patients. Two patients had collum femoris fractures at different times and were treated with hemiarthroplasty.

A cemented femoral stem (Spectron, Smith & Nephew) was selected for all patients; 18 received a bipolar femoral head and 26 received a unipolar femoral head. There was no statistical difference between bipolar and unipolar heads with regard to patient hip dislocation rates. (p=0.149)

The average duration of hemodialysis treatment prior to fracture occurrence was 10.3 years (range: 4 months–25 years). Mean preoperative hemoglobin and hematocrit levels were 7.96 mg/dl and 22.4%, respectively. (range: 6.1 mg/dl–9.7 mg/dl and 16.3%–28.5%, standard deviation: 1.31 mg/dl and 3.01%). Mean postoperative blood loss was 900 cc (range: 200 cc–3000 cc, standard deviation: 250 cc) and mean transfusion volume was 2.7 units of erythrocyte suspensions (range: 2–8, standard deviation: 1.47). Mean duration of hospital stay was 19.74 days (range: 8–120 days, standard deviation: 4.68).

The most common complication (8 patients) was bleeding in our patient series. The other complications were early prosthetic infection (2 patients), hip dislocation (1 patient), myocardial infarction during hospital stay (2 patients), pulmonary embolism (1 patient), epidural cranial bleeding (1 patient), and sepsis due to cholecystitis during hospital stay (1 patient). (Table 1) The total complication rate in our patient sample was 38.1%. No correlation was found between complications and average duration of hemodialysis. (p=0.092)

Five patients died during hospitalization as a result of myocardial infarction (2 patients), pulmonary embolism (1 patient), sepsis (1 patient), and congestive heart failure in intensive care unit (1 patient). The mortality rate of the patients at the 1-year follow-up was 42.8% (18/42). At the last control evaluation, the mortality rate was 59.5% (25/42).

In the assessment of prosthesis survival, 2 patients required implant removal due to ongoing infection after debridement treatment, and did not undergo a revision procedure due to poor medical conditions. (Figure 1) One patient had an acetabular protrusion in the second year post-procedure and underwent a revision procedure

Table 1. Complications.

Complications:	Number of patients
Bleeding	8
Prosthetic infection	2
Hip dislocation	1
Pulmonary embolism	1
Myocardial infarction	2
Epidural cranial bleeding	1
Sepsis	1

entailing total hip arthroplasty. One patient had loosening of the femoral component and underwent a revision procedure in the seventh year of follow-up; this same patient had a periprosthetic femoral fracture after one year and was treated with osteosynthesis. (Figure 2) There were 17 living patients at the last follow-up, and the mean HHS of these patients was 74.5 (range: 43–85, standard deviation: 6.63).

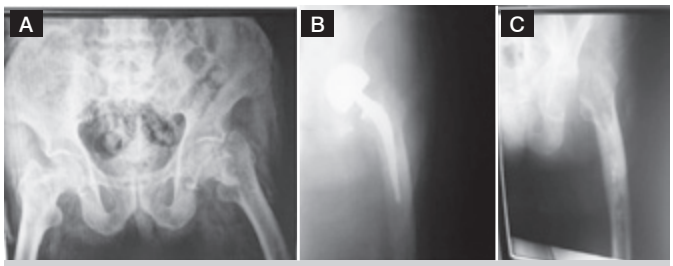

Figure 1. 80-year-old male patient with left collum femoris fracture. (A) Preoperative AP view of pelvis; (B) Postoperative AP view of left hip; (C) AP view of left hip after implant removal due to ongoing periprosthetic infection.

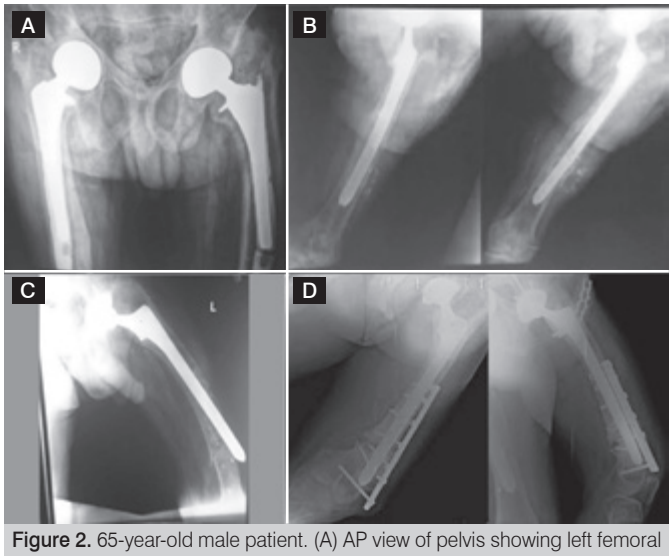

Figure 2. 65-year-old male patient. (A) AP view of pelvis showing left femoral component loosening at 7-year follow-up. (B) AP and lateral views of left hip after revision surgery. (C) AP view of left femur showing periprosthetic femoral fracture; (D) AP view of left femur after osteosynthesis of the fracture.

DISCUSSION

Treatment of collum femoris fractures in patients with chronic renal failure is still challenging because of the low bone mineral density in these patients.[1,2,5,6] Although the metabolic problems in these patients do not prevent fracture union, the risk of osteosynthesis failure is usually higher due to their low bone mineral density, and the literature favors arthroplasty, especially in middle-aged and older patients.[5,6] Although arthroplasty is a more sensible treatment option in comparison to osteosynthesis, the complications and outcomes of arthroplasty are not well known in this special group of patients because the literature on this topic is limited.[6,10] Our study evaluated the midterm functional results, complications, and morbidity and mortality rates in patients with end-stage chronic renal failure who had collum femoris fractures and were treated with hemiarthroplasty.

There are some studies in the literature that investigate the results of hip fracture treatment in patients with chronic renal failure.[10-12] Karaeminoğulları et al.[10] retrospectively evaluated 29 patients with renal failure in three groups (osteosynthesis of intertrochanteric fractures, arthroplasty of collum femoris fractures, and osteosynthesis of collum femoris fractures) and suggested arthroplasty instead of osteosynthesis in collum femoris fractures in chronic renal failure patients because of high complication rates in these patients.[10] These authors reported 1 complication in 8 arthroplasty operations (12.5%).[10] Another study from Poland reported hemiarthroplasty results in 12 patients with chronic renal failure (mean age: 51 years) and did not observe any serious complications, other than one acetabular protrusion 20 months after surgery.[11] In our study we had a more homogeneous group of 42 patients and 44 hips. In comparison to these previous studies, our complication rate of 38.1% was notably higher. We also had 2 cases which required revision surgery, and at the last control evaluation, prosthesis survival of our living patients was 76.4% with mean follow-up of 52.3 months.

Bleeding was the most common complication in our patients, and 2 patients required secondary surgery for hematoma evacuation. This complication may result from the use of heparin to prevent coagulation during hemodialysis. On the other hand, these patients had coagulopathy problems, and in addition to the risk of hip fracture these patients are more prone to vascular complications. Although all patients received prophylaxis with low-molecular-weight heparin, 2 patients had myocardial infarction and 1 patient had a pulmonary embolism. Infection is another common complication, and prosthetic infection varies from 0 to 19% between different patient series.[6,12] This high risk of periprosthetic infection may be related to mismanagement of hematoma in the postoperative period. In our series, we had 2 periprosthetic infections (4.7%). Although these infections were diagnosed in the early postoperative period, both patients required implant removal due to ongoing infection after debridement treatment and did not receive revision surgery because of their poor medical condition.

In another study, Klein et al.[13] reported treatment results for 9 hips in 8 patients (5 osteosynthesis, 4 arthroplasty). In this small series no wound infections, thromboembolic events, or hemorrhagic complications were reported, but these authors did note a 38% mortality rate in the first year after surgery. The mortality rate for senile osteoporotic hip fractures without chronic renal failure has been reported in different series as 11–24%.[14] In our patients, the first-year mortality rate was 42.8%. This difference may be associated with comorbidities such as cardiovascular, endocrine, gastrointestinal, and infectious diseases related to chronic renal failure.

Sakabe et al.[15] evaluated life expectancy and function after collum femoris fractures in a total of 71 hemodialysis patients; 13 were treated non-surgically, 34 received hemiarthroplasty and 24 received internal fixation. In 34 patients who underwent hemiarthroplasty, these authors reported 14.7% dislocation of prosthesis, 8.6% bleeding, and 1.7% infection. The entire patient group in this study underwent evaluation for returning to daily living activities, and the authors reported that over 50% of the patients had returned to these activities at 1 year after surgery.[15] Complication rates for this patient series were similar to those found in this present study. In comparison to this study, we evaluated functional status in 17 living patients at the last follow-up and found a mean HHS score of 74.5 (range 43–85).

The main limitations of our study were its retrospective nature and the lack of a matched control group comprised of non-hemodialysis patients with collum femoris fractures. However, our patient series is one of the largest in the literature and to our knowledge is the only study evaluating the complications and midterm outcomes of hemiarthroplasty treatment alone in this special group of patients.

CONCLUSION

Collum femoris fractures are more common in hemodialysis patients because of metabolic bone disease in chronic renal failure. In addition to low bone mineral density, these patients had many comorbidities such as coronary artery disease and coagulopathies, and these problems may exacerbate the high complication rates (38.1%) and high first-year mortality rates (42.8%) in these patients. Orthopedic surgeons should consider this high complication rate and inform patients and their families about the consequences of this treatment.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. AS (0000-0001-9448-6416)*, KS (0000-0002-4759-4729)* and GP (0000-0002-9184-8730)* were the main contributors in drafting the manuscript. ÖY (0000-0001-5250-2887)*, ONE (0000-0001-6848-6930)*, GP and AS performed surgeries and followed the patients. KŞ gathered clinical data and performed the statistical analysis. TA (0000-0002-0704-3797)* and ONE performed the literature search. ÖY contributed to the intellectual concept of the study. All the authors actively participated in discussing the results and reviewed and approved the final version of this manuscript. *ORCID (Open Researcher and Contributor ID).

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acheflan

Cordia verbenacea DC. 5 mg

alfa-humuleno

SUPERIORIDADE
ao diclofenaco dietilamônio tópico[2**]

DOR CRÔNICA
Eficaz no tratamento de tendinite crônica e dor miofascial[2,3]

DOR AGUDA
excelente eficácia em casos de afecções musculoesqueléticas[2,3**]

INTEGRIDADE
As vibrações do US (fonoforese) não alteram os princípios ativos[4,5]

1º MEDICAMENTO 100% BRASILEIRO[1]

Pesquisa e Desenvolvimento Aché em Parceria com CPQBA UNICAMP

*Equivalente a 0,130mg de alfa-humuleno[6,7]
**Considerada superior ao diclofenaco dietilamônio nos casos de tendinite crônica[3]

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CONTRAINDICAÇÕES: INDIVÍDUOS SENSÍVEIS A CORDIA VERBENACEA DC. OU A QUALQUER COMPONENTE DA FÓRMULA. INTERAÇÕES MEDICAMENTOSAS: NÃO HOUVE RELATO DE INTERAÇÃO MEDICAMENTOSA NOS ESTUDOS CONDUZIDOS PARA AVALIAÇÃO DO ACHEFLAN.

ACHEFLAN. Cordia verbenacea DC - MS - 1.0573.0341. **Indicações: ACHEFLAN** é indicado nas seguintes situações: tendinites, afecções músculo-esqueléticas associadas à dor e inflamação, como dor miofascial (como dorsalgia e lombalgia), em quadros inflamatórios dolorosos associados a traumas de membros, entorses e contusões. **Contra-indicações: ACHEFLAN é contra-indicado nas seguintes situações: Indivíduos sensíveis a *Cordia verbenacea DC.* ou a qualquer componente da fórmula. Ocorrência de soluções de continuidade (feridas, queimaduras, lesões infeccionadas, etc). Advertências: ACHEFLAN** É PARA USO EXTERNO E NÃO DEVE SER INGERIDO. NÃO DEVE SER UTILIZADO ASSOCIADO A OUTROS PRODUTOS DE USO TÓPICO. RARAMENTE PODE CAUSAR AUMENTO DA SENSIBILIDADE LOCAL. TESTES REALIZADOS EM ANIMAIS INDICAM QUE **ACHEFLAN** NÃO APRESENTA ATIVIDADE IRRITANTE NA MUCOSA OCULAR. ENTRETANTO, RECOMENDA-SE LAVAR ABUNDANTEMENTE O LOCAL COM ÁGUA EM CASO DE CONTATO COM OS OLHOS. **Uso em idosos, crianças e outros grupos de risco:** não existe experiência clínica sobre o uso de **ACHEFLAN** em idosos, crianças abaixo de 12 anos, gestantes e lactantes. **Gravidez e lactação:** categoria de risco na gravidez C: Não foram realizados estudos em animais prenhes e nem em mulheres grávidas. "ESTE MEDICAMENTO NÃO DEVE SER UTILIZADO DURANTE A GESTAÇÃO OU AMAMENTAÇÃO SEM ORIENTAÇÃO MÉDICA". **Interações medicamentosas:** não houve relato de interação medicamentosa nos estudos conduzidos para avaliação do **ACHEFLAN**. Entretanto sua associação a outros fármacos deverá ser avaliada pelo médico. **Reações adversas:** O USO DE **ACHEFLAN** NÃO ESTÁ ASSOCIADO A RELATO DE REAÇÕES ADVERSAS. RARAMENTE PODE CAUSAR AUMENTO DA SENSIBILIDADE LOCAL. "ATENÇÃO: ESTE É UM MEDICAMENTO NOVO E, EMBORA AS PESQUISAS TENHAM INDICADO EFICÁCIA E SEGURANÇA ACEITÁVEIS PARA COMERCIALIZAÇÃO, EFEITOS INDESEJÁVEIS E NÃO CONHECIDOS PODEM OCORRER. NESTE CASO, INFORME SEU MÉDICO." **Posologia:** aplicação tópica, sobre a pele íntegra, de 8 em 8 horas. A duração do tratamento varia conforme a afecção que se pretende tratar. Nos ensaios clínicos a duração do tratamento variou entre 1 a 2 semanas podendo ser prolongado até 4 semanas. Farmacêutica Responsável: Gabriela Mallmann - CRF-SP nº 30.138. **VENDA SOB PRESCRIÇÃO MÉDICA.** MB03 SAP 4052805 e SAP 4053004

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carisoprodol, cafeína
diclofenaco sódico, paracetamol

Uma relação de confiança se constrói com o tempo!

Referências Bibliográficas:1. Internal Report – CLOSE UP Junho/2017.

Contraindicação: Hipersensibilidade a qualquer dos componentes da fórmula. Interação Medicamentosa: A administração concomitante de glicocorticóides e outros agentes anti-inflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais.

TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

TANDRILAX (cafeína 30 mg / carisoprodol 125 mg / diclofenaco sódico 50 mg / paracetamol 300 mg) Comprimidos. USO ORAL. USO ADULTO. Indicações: Tratamento de reumatismo nas suas formas inflamatório-degenerativas agudas e crônicas; crises agudas de gota, estados inflamatórios agudos, pós-traumáticos e pós-cirúrgicos. Exacerbações agudas de artrite reumatóide e osteo-artrose e estados agudos de reumatismo nos tecidos extra-articulares e como coadjuvante em processos inflamatórios graves decorrentes de quadros infecciosos. **Contraindicações: Nos casos de úlcera péptica em atividade; hipersensibilidade a quaisquer dos componentes de sua fórmula; discrasias sanguíneas; diáteses hemorrágicas (trombocitopenia, distúrbios da coagulação), porfiria; insuficiência cardíaca, hepática ou renal grave; hipertensão grave. É contra-indicado em pacientes asmáticos nos quais são precipitados acessos de asma, urticária ou rinite aguda pelo ácido acetilsalicílico e demais inibidores da via da cicloxigenase da síntese de prostaglandinas. Precauções e Advertências: O uso em pacientes idosos, geralmente mais sensíveis aos medicamentos, deve ser cuidadosamente observado. Desaconselha-se o uso do TANDRILAX durante a gravidez e lactação. A possibilidade de reativação de úlceras pépticas requer anamnese cuidadosa quando houver história pregressa de dispepsia, hemorragia gastrintestinal ou úlcera péptica. Nas indicações do TANDRILAX por períodos superiores a dez dias, deverá ser realizado hemograma e provas de função hepática antes do início do tratamento e, periodicamente, a seguir. A diminuição da contagem de leucócitos e/ou plaquetas, ou do hematócrito requer a suspensão da medicação. Em pacientes portadores de doenças cardiovasculares, a possibilidade de ocorrer retenção de sódio e edema deverá ser considerada. Observando-se reações alérgicas pruriginosas ou eritematosas, febre, icterícia, cianose ou sangue nas fezes, a medicação deverá ser imediatamente suspensa. Não use outro produto que contenha paracetamol. Não é indicado para crianças abaixo de 14 anos, com exceção de casos de artrite juvenil crônica. Interações medicamentosas:** O diclofenaco sódico, constituinte do TANDRILAX, pode elevar a concentração plasmática de lítio ou digoxina, quando administrado concomitantemente com estas preparações. Alguns agentes antiinflamatórios não-esteróides são responsáveis pela inibição da ação de diuréticos da classe da furosemida e pela potenciação de diuréticos poupadores de potássio, sendo necessário o controle periódico dos níveis séricos de potássio. A administração concomitante de glicocorticóides e outros agentes antiinflamatórios não-esteróides pode levar ao agravamento de reações adversas gastrintestinais. A biodisponibilidade do TANDRILAX é alterada pelo ácido acetilsalicílico quando este composto é administrado conjuntamente. Recomenda-se a realização de exames laboratoriais periódicos quando anticoagulantes forem administrados juntamente com TANDRILAX, para aferir se o efeito anticoagulante desejado está sendo mantido. Pacientes em tratamento com metotrexato devem abster-se do uso do TANDRILAX nas 24 horas que antecedem ou que sucedem sua ingestão, uma vez que a concentração sérica pode elevar-se, aumentando a toxicidade deste quimioterápico. **Reações adversas: Distúrbios gastrintestinais como dispepsia, dor epigástrica, recorrência de úlcera péptica, náuseas, vômitos e diarréia. ocasionalmente, podem ocorrer cefaléia, sonolência, confusão mental, tonturas, distúrbios da visão, edema por retenção de eletrólitos, hepatite, pancreatite, nefrite intersticial. Foram relatadas raras reações anafilactóides urticariformes ou asmatiformes bem como síndrome de stevens-johnson e síndrome de lyell, além de leucopenia, trombocitopenia, pancitopenia, agranulocitose e anemia aplástica. o uso prolongado pode provocar necrose papilar renal. TANDRILAX é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas. Posologia:** A dose mínima diária recomendada é de um comprimido a cada 12 horas e a duração do tratamento deve ser a critério médico e não deverá ultrapassar 10 dias. Tratamentos mais prolongados requerem observações especiais (vide "Precauções"). Os comprimidos do TANDRILAX deverão ser ingeridos inteiros (sem mastigar), às refeições, com auxílio de líquido. "SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO." VENDA SOB PRESCRIÇÃO MÉDICA - MS - 1.0573.0055 - MB 08 - SAP 4104203

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ALÍVIO COM[1,2]

dorene pregabalina

Rápido, eficaz e seguro no tratamento da fibromialgia.[3]

Redução da dor
a partir da primeira semana de tratamento na fibromialgia[4]

A pregabalina é eficaz
em reduzir a dor dos pacientes com fibromialgia[5]

Melhora da disfunção do sono
relacionada à fibromialgia.[6]
Grande parte desse benefício foi devido:[6]

- Efeito da pregabalina na insônia[6]
- Atividade analgésica do medicamento[6]

Referências Bibliográficas: 1) TOLLE, T. et al. Pregabalin for relief of neuropathic pain associated with diabetic neuropathy: a randomized, double-blind study. European Journal of Pain, v. 12, n. 2, p. 203-213, 2008. 2) OHTA, H. et al. A randomized, double-blind, multicenter, placebo-controlled phase III trial to evaluate the efficacy and safety of pregabalin in Japanese patients with fibromyalgia. Arthritis Research & Therapy, v. 14, N. 217, 2012. 3) BOOMERSHINE, C. S. Pregabalin for the management of fibromyalgia syndrome. Journal of Pain Research, v. 3, p. 81-88, 2010. 4) PAUER, L. et al. An international, randomized, double-blind, placebo-controlled, phase III trial of pregabalin monotherapy in treatment of patients with fibromyalgia. J Rheumatol, v. 38, n. 12, p. 2643-2652, 2011. 5) HEYMANN, R.E. et al. Consenso Brasileiro do tratamento da fibromialgia. Rev Bras Reumatol, v. 50, n.1, p.56-66, 2010. - A pregabalina é eficaz em reduzir a dor dos pacientes com fibromialgia (grau de recomendação A, nível de evidência 1b. Página 60, coluna 1, 5º parágrafo. - Consenso brasileiro do tratamento da fibromialgia, que inclui a pregabalina no tratamento da fibromialgia com grau de recomendação A e nível de evidência 1B. 6) RUSSELL, I.J. et al. The effects of pregabalin on sleep disturbance symptoms among individuals with fibromyalgia syndrome. Sleep Med., v. 10, n. 6, p. 604-610, 2009.

DORENE (pregabalina) 75 mg e 150 mg. Cápsula. USO ORAL. USO ADULTO E PEDIÁTRICO ACIMA DE 12 ANOS (vide Indicações). Indicações: Dor Neuropática; Epilepsia; Transtorno de Ansiedade Generalizada (TAG); Fibromialgia. Contraindicações: Dorene é contraindicado a pacientes com hipersensibilidade conhecida à pregabalina ou a qualquer componente da fórmula. Precauções e advertências: **Pacientes com problemas hereditários raros de intolerância a galactose, deficiência de lactase ou má- absorção de glicose-galactose não devem utilizar pregabalina cápsulas. Alguns pacientes diabéticos sob tratamento com pregabalina que obtiverem ganho de peso podem necessitar de ajuste da medicação hipoglicêmica. Houve relatos de reações de hipersensibilidade, incluindo casos de angioedema. Pregabalina deve ser descontinuado imediatamente se ocorrerem sintomas de angioedema, tais como edema facial, perioral ou da via aérea superior. O tratamento com pregabalina está associado com tontura e sonolência, que pode aumentar a ocorrência de acidentes (queda) na população idosa. Pacientes devem ser alertados para ter cautela até que os efeitos potenciais de pregabalina sejam familiares. Visão borrada transitória e outras alterações na acuidade visual foram reportadas por pacientes tratados com pregabalina. A descontinuação da pregabalina pode resultar na resolução ou melhora desses sintomas visuais. Foram observados sintomas de retirada em alguns pacientes após a descontinuação do tratamento prolongado e de curto prazo com pregabalina. Os seguintes eventos foram mencionados: insônia, dor de cabeça, náusea, ansiedade, hiperidrose e diarreia (vide item Reações Adversas). Como é o caso com qualquer droga ativa do SNC, deve-se avaliar cuidadosamente o histórico de pacientes quanto ao abuso de drogas e observá-los quanto a sinais de abuso da pregabalina. Foi relatada melhora da função renal após a descontinuação ou redução da dose de pregabalina. Houve relatos pós-comercialização de insuficiência cardíaca congestiva em alguns pacientes recebendo pregabalina. Devido aos dados limitados de pacientes com insuficiência cardíaca congestiva grave, Dorene deve ser administrado com cautela nesses pacientes (vide item 9. Reações Adversas).** Efeitos sobre a Habilidade de Dirigir e Operar Máquinas: Dorene pode produzir tontura e sonolência que, portanto, podem prejudicar a habilidade de dirigir e operar máquinas. Os pacientes devem ser aconselhados a não dirigir, operar máquinas complexas, ou se engajar em outras atividades potencialmente perigosas até que se saiba se este medicamento afeta a sua capacidade de executar tais atividades. Uso em Idosos, Crianças e Outros Grupos de Risco: Vide item Posologia. Gravidez e lactação: Uso durante a Gravidez: Não há dados adequados sobre o uso de pregabalina em mulheres grávidas. Estudos em animais mostraram toxicidade reprodutiva. O risco potencial a humanos é desconhecido. Portanto, Dorene não deve ser utilizado durante a gravidez. Métodos contraceptivos eficazes devem ser utilizados por mulheres com potencial de engravidar. **A pregabalina é um medicamento classificado na categoria C de risco de gravidez. Portanto, este medicamento não deve ser utilizado por mulheres grávidas sem orientação médica ou do cirurgião-dentista.** Uso durante a Lactação: Não se sabe se a pregabalina é excretada no leite materno de humanos. Entretanto, está presente no leite de ratas. Portanto, a amamentação não é recomendada durante o tratamento com Dorene. **Interações medicamentosas:** A pregabalina provavelmente não inibe o metabolismo de fármacos ***in vitro*** e nem se liga a proteínas plasmáticas. A pregabalina pode potencializar os efeitos do etanol e lorazepan. A pregabalina parece ser aditiva no prejuízo da função cognitiva e coordenação motora grosseira causado pela oxicodona. Em experiência pós-comercialização, houve relatos de insuficiência respiratória e coma em pacientes sob tratamento de pregabalina e outros medicamentos antidepressivos do SNC. Há relatos pós-comercialização de eventos relacionados à redução da função do trato gastrintestinal inferior (por ex, obstrução intestinal, íleo paralítico, constipação) quando a pregabalina foi coadministrada com medicamentos que têm o potencial para produzir constipação, tais como analgésicos opioides. Não foram conduzidos estudos de interação farmacodinâmica específica em voluntários idosos. Reações adversas: **As reações adversas mais comuns foram tontura e sonolência, em geral, de intensidade leve a moderada. As reações adversas comuns foram: Aumento de apetite, Confusão, desorientação, irritabilidade, humor eufórico, diminuição da libido, insônia, Ataxia, coordenação anormal, transtorno de equilíbrio, amnésia, distúrbios de atenção, dificuldade de memória, tremores, disartria, parestesia, sedação, letargia, Visão turva, diplopia, Vertigem, Vômitos, distensão abdominal, constipação, boca seca, flatulência, disfunção erétil, edema periférico, edema, marcha anormal, sensação de embriaguez, sensação anormal, fadiga e aumento de peso. As seguintes reações adversas foram relatadas durante a pós-comercialização: Sistema imune: angioedema, reação alérgica, hipersensibilidade. Sistema nervoso: dor de cabeça, perda de consciência, prejuízo mental.** Oftalmológicos: cerátite. Cardíacos: insuficiência cardíaca congestiva. Respiratório e torácico: edema pulmonar. Gastrintestinais: edema de língua, diarreia, náusea. Pele e tecido subcutâneo: inchaço da face, prurido. Renais e urinários: retenção urinária. Reprodutor e mamas: ginecomastia. Geral: mal-estar. Idosos (acima de 65 anos de idade). Num total de 998 pacientes idosos, não foram observadas diferenças quanto a segurança geral, em comparação aos pacientes com menos de 65 anos de idade. Posologia: Dorene deve ser utilizado por via oral, com ou sem alimentos. Cada cápsula de Dorene contêm 75 mg ou 150 mg de pregabalina. Dor Neuropática: A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Para a maioria dos pacientes, 150 mg duas vezes ao dia é a dose ideal. Com base na resposta individual e na tolerabilidade do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após um intervalo de 3 a 7 dias e, se necessário, até uma dose máxima de 300 mg duas vezes ao dia após mais uma semana. Epilepsia: A dose inicial recomendada de Dorene é de 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos. Com base na resposta e tolerabilidade individuais do paciente, a dose poderá ser aumentada para 150 mg duas vezes ao dia após 1 semana. A dose máxima de 300 mg duas vezes ao dia pode ser atingida após mais 1 semana. Transtorno de Ansiedade Generalizada (TAG): A dose varia de 150 a 600 mg/dia, divididas em duas ou três doses. A necessidade para o tratamento deve ser reavaliada regularmente. Fibromialgia: A dose recomendada de Dorene é de 300 a 450 mg/dia. A dose deve ser iniciada com 75 mg duas vezes ao dia (150 mg/dia), com ou sem alimentos, e a dose pode ser aumentada para 150 mg duas vezes ao dia (300 mg/dia) em uma semana baseado na eficácia e tolerabilidade individuais. Descontinuação do Tratamento: Se Dorene for descontinuado, recomenda-se que isto seja feito gradualmente durante no mínimo 1 semana. Uso em Pacientes com Insuficiência Renal: A redução da dosagem em pacientes com a função renal comprometida deve ser individualizada de acordo com o clearance de creatinina. Para pacientes submetidos à hemodiálise, a dose diária de Dorene deve ser ajustada com base na função renal. Além da dose diária, uma dose suplementar deve ser administrada imediatamente após cada tratamento de 4 horas de hemodiálise. Uso em Pacientes com Insuficiência Hepática: Nenhum ajuste de dose é necessário para pacientes com insuficiência hepática. Uso em Crianças: A segurança e a eficácia de pregabalina em pacientes pediátricos abaixo de 12 anos de idade ainda não foram estabelecidas. O uso em crianças não é recomendado. Uso em Adolescentes (12 a 17 anos de idade): Pacientes adolescentes com epilepsia podem receber a dose como adultos. A segurança e a eficácia de pregabalina em pacientes abaixo de 18 anos de idade com dor neuropática não foram estabelecidas. Uso em Pacientes Idosos (acima de 65 anos de idade): Pacientes idosos podem necessitar de redução da dose de Dorene devido à diminuição da função renal. Dose Omitida: Caso o paciente esqueça de tomar Dorene no horário estabelecido, deve tomá-lo assim que lembrar. Entretanto, se já estiver perto do horário de tomar a próxima dose, deve desconsiderar a dose esquecida e tomar a próxima. **Este medicamento não pode ser partido, aberto ou mastigado.** SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. **VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA.** MS - 1.0573.0457. MB 02_VP SAP 4475900.

Contraindicações: Dorene não deve ser utilizado se você tem hipersensibilidade (alergia) conhecida à pregabalina ou a qualquer componente da fórmula.
Interações medicamentosas: A pregabalina pode potencializar o efeito da oxicodona (analgésico), bebidas alcoólicas e de lorazepam (tranquilizante).

DORENE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

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HÁ 13 ANOS CONSTRUINDO

histórias de sucesso[1]

ARTROLIVE

sulfato de glicosamina+sulfato de condroitina

PIONEIRISMO* & LIDERANÇA[1,2]
NO TRATAMENTO DA OSTEOARTRITE[3,4]

Novas evidências

Estudo demonstrou que os participantes **que tomaram sulfato de glucosamina + sulfato de condroitina reduziram a perda de volume de cartilagem após 24 meses**, argumentando para um efeito modificador da doença.[5]

*Pioneirismo refere-se ao lançamento do produto à classe médica.

Referências Bibliográficas: 1. 1. Internal Report. Dados de auditoria IMS Health. Fevereiro/2017. **2.** Internal Report. Dados de auditoria IMS-PMB. Fevereiro/2017. **3.** Bula do produto ARTROLIVE: cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **4.** Bula do produto ARTROLIVE: granulado em sachê. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5.** MARTEL-PELLETIER, J. et al. First-line analysis of the effects of treatment on progression of structural changes in knee osteoarthritis over 24 months: data from the osteoarthritis initiative progression cohort. Ann Rheum Dis, v. 74, n. 3, p. 547-556, 2015.

Contraindicação: Pacientes que apresentem hipersensibilidade a quaisquer dos componentes de sua fórmula. Interação medicamentosa: É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com Artrolive.

ARTROLIVE CAPS. sulfato de glicosamina + sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. Portanto, o uso concomitante de **ARTROLIVE** com anticoagulantes orais deve levar em conta avaliações rigorosas do INR. **Reações adversas: SISTEMA CARDIOVASCULAR:** EDEMA PERIFÉRICO E TAQUICARDIA. JÁ FORAM RELATADOS COM O USO DA GLICOSAMINA, PORÉM NÃO FOI ESTABELECIDA UMA RELAÇÃO CAUSAL. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **SISTEMA NERVOSO CENTRAL:** MENOS DE 1% DOS PACIENTES EM ESTUDOS CLÍNICOS APRESENTARAM CEFALEIA, INSÔNIA E SONOLÊNCIA NA VIGÊNCIA DO TRATAMENTO COM A GLICOSAMINA. **ENDÓCRINO-METABÓLICO:** ESTUDOS RECENTES DEMONSTRARAM QUE A ASSOCIAÇÃO CONDROITINA E GLICOSAMINA, QUANDO EMPREGADA EM PACIENTES PORTADORES DE DIABETES MELLITUS TIPO II, NÃO LEVOU A ALTERAÇÕES NO METABOLISMO DA GLICOSE. OS RESULTADOS DESTES ESTUDOS NÃO PODEM SER EXTRAPOLADOS PARA PACIENTES COM DIABETES MELLITUS DESCOMPENSADO OU NÃO-CONTROLADO. É RECOMENDÁVEL QUE PACIENTES DIABÉTICOS MONITOREM SEUS NÍVEIS SANGUÍNEOS DE GLICOSE MAIS FREQUENTEMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. **GASTRINTESTINAL:** NÁUSEA, DISPEPSIA, VÔMITO, DOR ABDOMINAL OU EPIGÁSTRICA, CONSTIPAÇÃO, DIARREIA, QUEIMAÇÃO E ANOREXIA TÊM SIDO RARAMENTE DESCRITOS NA LITERATURA NA VIGÊNCIA DE TRATAMENTO COM GLICOSAMINA E CONDROITINA. **PELE:** ERITEMA, PRURIDO, ERUPÇÕES CUTÂNEAS E OUTRAS MANIFESTAÇÕES ALÉRGICAS DE PELE FORAM REPORTADAS EM ENSAIOS CLÍNICOS COM GLICOSAMINA. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. **POSOLOGIA: Adultos:** Recomenda-se iniciar a terapêutica com a prescrição de 1 cápsula via oral 3 vezes ao dia. Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4470700. **ARTROLIVE**. 1,5 g sulfato de glicosamina + 1,2 g sulfato de condroitina. MS – 1.0573.0286. **INDICAÇÕES: ARTROLIVE** é indicado para osteoartrite, osteoartrose ou artrose em todas as suas manifestações. **CONTRAINDICAÇÕES: ARTROLIVE** É CONTRAINDICADO EM PACIENTES QUE APRESENTEM HIPERSENSIBILIDADE A QUAISQUER DOS COMPONENTES DE SUA FÓRMULA, GRAVIDEZ E LACTAÇÃO. **PRECAUÇÕES E ADVERTÊNCIAS:** SÃO NECESSÁRIOS O DIAGNÓSTICO PRECISO E O ACOMPANHAMENTO CUIDADOSO DE PACIENTES COM SINTOMAS INDICATIVOS DE AFECÇÃO GASTRINTESTINAL, HISTÓRIA PREGRESSA DE ÚLCERA GÁSTRICA OU INTESTINAL, DIABETES MELLITUS, OU A CONSTATAÇÃO DE DISTÚRBIOS DO SISTEMA HEMATOPOIÉTICO OU DA COAGULAÇÃO SANGUÍNEA ASSIM COMO PORTADORES DE INSUFICIÊNCIA DAS FUNÇÕES RENAL, HEPÁTICA OU CARDÍACA. SE OCORRER EVENTUALMENTE ULCERAÇÃO PÉPTICA OU SANGRAMENTO GASTRINTESTINAL EM PACIENTES SOB TRATAMENTO, A MEDICAÇÃO DEVERÁ SER SUSPENSA IMEDIATAMENTE. DEVIDO À INEXISTÊNCIA DE INFORMAÇÕES TOXICOLÓGICAS DURANTE O PERÍODO GESTACIONAL, **ARTROLIVE** NÃO ESTÁ INDICADO PARA SER UTILIZADO DURANTE A GRAVIDEZ. NÃO EXISTEM INFORMAÇÕES SOBRE A PASSAGEM DO MEDICAMENTO PARA O LEITE MATERNO SENDO DESACONSELHADO SEU USO NESSAS CONDIÇÕES E AS LACTANTES SOB TRATAMENTO NÃO DEVEM AMAMENTAR. PODE OCORRER FOTOSSENSIBILIZAÇÃO EM PACIENTES SUSCETÍVEIS, PORTANTO PACIENTES COM HISTÓRICO DE FOTOSSENSIBILIDADE A OUTROS MEDICAMENTOS DEVEM EVITAR SE EXPOR À LUZ SOLAR. FORAM DESCRITOS NA LITERATURA, ALGUNS CASOS DE HIPERTENSÃO SISTÓLICA REVERSÍVEL, EM PACIENTES NÃO PREVIAMENTE HIPERTENSOS, NA VIGÊNCIA DO TRATAMENTO COM GLICOSAMINA E CONDROITINA. PORTANTO, A PRESSÃO ARTERIAL DEVE SER VERIFICADA PERIODICAMENTE DURANTE O TRATAMENTO COM **ARTROLIVE**. FORAM RELATADOS POUCOS CASOS DE PROTEINÚRIA LEVE E AUMENTO DA CREATINO-FOSFOQUINASE (CPK) DURANTE TRATAMENTO COM GLICOSAMINA E CONDROITINA, QUE VOLTARAM AOS NÍVEIS NORMAIS APÓS INTERRUPÇÃO DO TRATAMENTO. **INTERAÇÕES MEDICAMENTOSAS:** O tratamento concomitante com antiinflamatórios não-esteroidais pode incorrer no agravamento de reações adversas do sistema gastrintestinal, sendo recomendado um acompanhamento médico mais rigoroso nesses casos. Alguns autores da literatura médica descrevem que o uso de glicosamina e condroitina pode incorrer em um aumento da resistência à insulina, porém, esses estudos foram realizados com doses muito superiores às indicadas na terapêutica clínica normal e sua validade ainda é discutida por vários outros autores. Estudos recentes demonstraram que a associação condroitina e glicosamina, quando empregada em pacientes portadores de diabetes mellitus tipo II, não levou a alterações no metabolismo da glicose. Os resultados destes estudos não podem ser extrapolados para pacientes com diabetes mellitus descompensado ou não-controlado. É recomendável que pacientes diabéticos monitorem seus níveis sanguíneos de glicose mais frequentemente durante o tratamento com **ARTROLIVE**. O uso concomitante de **ARTROLIVE** com os inibidores da topoisomerase II (etoposídeo, teniposídeo e doxorrubicina) deve ser evitado, uma vez que a glicosamina induziu resistência in vitro a estes medicamentos em células humanas cancerosas de cólon e de ovário. O tratamento concomitante de **ARTROLIVE** com anticoagulantes como o acenocoumarol, dicumarol, heparina e varfarina, pode levar ao aumento das chances de sangramento, devido a alterações nos valores de INR (International Normalized Ratio). Há relato de um caso na literatura de potencialização do efeito da varfarina, com consequente aumento dos valores sanguíneos de INR. 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Como os efeitos do medicamento se iniciam em média após a terceira semana de tratamento deve-se ter em mente que a continuidade e a não-interrupção do tratamento são fundamentais para se alcançar os benefícios analgésicos e de mobilidade articular. **SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA.** MB03a SAP4406702.

Material técnico-científico de distribuição exclusiva à classe médica.

A ação eficaz[1] no tratamento da Osteoartrite.

Glicolive
sulfato de glicosamina

Qualidade Aché e preço acessível para o tratamento da OA.[2-5]

Referências Bibliográficas: 1) MATHESON, A. J; PERRY, C. M. Glucosamine: a review of its use in the management of osteoarthritis. Drugs Aging, v. 20, n. 14, p. 1041-60, 2003. **2)** Kairos Web Brasil. Disponível em: http://brasil.kairosweb.com Acesso em: Agosto/16. **3)** Programa Cuidados pela Vida (" O Programa Cuidados pela Vida pode alterar ou interromper esta campanha sem aviso prévio". Desconto calculado sobre o Preço Máximo ao Consumidor)". **4)** Bula do produto GLICOLIVE: pó para solução oral. Farmacêutica Responsável: Gabriela Mallmann, Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A. **5)** BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. Resolução - RE nº 1.101, de 9 de abril de 2015. Concede Certificação de Boas Práticas de Fabricação ao Aché. Diário Oficial da União, Brasília DF, p. 133, 9 abr 2015. **6)** Internal Report.

Contraindicações: hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol.

GLICOLIVE é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

GLICOLIVE (sulfato de glicosamina) 1500 mg pó para solução oral. USO ORAL. USO ADULTO. **Indicações:** GLICOLIVE é indicado no tratamento deartrose ou osteoartrite primária e secundária e suas manifestações. Contraindicações: **GLICOLIVE é contra-indicado em pacientes com hipersensibilidade a glicosamina ou a qualquer outro componente da fórmula. Não deve ser utilizado durante a gravidez, lactação ou em fenilcetonúricos. Cuidados e advertências: informar ao médico caso esteja utilizando outros medicamentos. Recomenda-se cautela em pacientes com sintomas indicativos de distúrbios gastrintestinais, história de úlcera gástrica ou intestinal, diabetes mellitus, portadores de insuficiência renal, hepática ou cardíaca. Caso ocorra ulceração péptica ou sangramento gastrintestinal a medicação deverá ser suspensa imediatamente. Recomenda-se evitar a ingestão de bebidas alcoólicas, durante o tratamento.** Gravidez e lactação: não há dados com relação ao uso de GLICOLIVE na gravidez e lactação humana, portanto, seu uso não é recomendado nestes casos. Interações medicamentosas: o sulfato de glicosamina pode favorecer a absorção gastrintestinal de tetraciclinas e reduzir a de penicilina e cloranfenicol. Não existe limitação para administração simultânea de analgésicos ou anti-inflamatórios esteroides e não esteroides. **Reações adversas: os efeitos colaterais mais comuns são de origem gastrintestinal, de intensidade leve a moderada, consistindo em desconforto gástrico, diarreia, náusea, prurido e cefaléia. Reações hematológicas: não foram observadas alterações clínicas significativas.Testes laboratoriais: não se observaram diferenças significativas nos valores médios nem nos dados individuais das provas laboratoriais e constantes vitais. Glicolive é um medicamento. "Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas."** Posologia: GLICOLIVE apresenta-se na forma de pó branco a levemente amarelado, com odor e sabor de abacaxi. Dispensar o conteúdo do envelope em um copo com água. Aguardar entre 2 a 5 minutos, mexer a solução com o auxílio de uma colher e consumir. Consumir 1 envelope por dia antes das refeições ou segundo indicação médica. A duração do tratamento fica a critério do médico. Para informações completas, consultar a bula na íntegra através da Central de Atendimento ao Cliente.VENDA SOB PRESCRIÇÃO MÉDICA. MS - 1.0573. 0403. MB05 SAP 4423401. "Material técnico científico de distribuição exclusiva à classe médica." SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO.

CAC Central de Atendimento a Clientes
0800 701 6900
cac@ache.com.br
8:00 h às 17:00 h (seg. a sex.)

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osteo muscular

achê
mais vida para você

Artrosil
lisinato de cetoprofeno

SMR
SMART MODULATED RELEASE[3]

O ÚNICO lisinato de cetoprofeno[1] com **TECNOLOGIA SMR[2,3]**

SEGURANÇA[2]
- Tolerabilidade gástrica 3 a 4 vezes maior comparado ao cetoprofeno comum.[2]

RÁPIDO INÍCIO DE AÇÃO[2]

EFICÁCIA[2]
- **Potência** anti-inflamatória, analgésica e antipirética superior ao cetoprofeno.[2]
- **Liberação prolongada:** Níveis plasmáticos mantidos por até 24h.[2,4]

Apresentações[4]
Cápsulas de liberação prolongada
de 160 e 320 mg com 10 e 20 cápsulas

Referências Bibliográficas: 1) ANVISA. Consulta de produtos. Disponível em: <http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_medicamento.asp>. Acesso em: Abr/2016. **2)** PELOGGIA, C.C.N.; BRITO NETO, A.J.; CUNHA, J. Avaliação da eficácia terapêuta e da tolerância do antiinflamatório lisinato de cetoprofeno, na forma cápsulas. Estudo multicêntrico aberto e não comparativo. Revista Brasileira de Medicina, v.57, n.6, p.617-624, 2000. **3)** Internal Report. **4)** Bula Do Produto ARTROSIL: Cápsulas. Farmacêutica Responsável: Gabriela Mallmann. Guarulhos, SP. Aché Laboratórios Farmacêuticos S.A.

Contraindicações: Úlcera péptica na fase ativa. Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.

ARTROSIL (lisinato de cetoprofeno) - 160 mg e 320 mg - Cápsulas de liberação prolongada - Uso oral - Uso Adulto - Indicações: Artrose, coxartrose, espondiloartrose, artrite reumatóide, bursite, flebite e tromboflebite superficial, contusão, entorse, luxação, distensão muscular. **Contraindicações: Úlcera péptica na fase ativa, anamnese positiva de úlcera péptica recorrente, dispepsia crônica, gastrite, insuficiência renal grave, leucopenia e plaquetopenia, grave distúrbio de hemocoagulação.** Hipersensibilidade a quaisquer componentes de sua fórmula. Existe a possibilidade de hipersensibilidade cruzada com ácido acetilsalicílico ou outros fármacos anti-inflamatórios não-esteroidais. Portanto, o cetoprofeno não deve ser administrado a pacientes nos quais o ácido acetilsalicílico ou outros fármacos antiinflamatórios não-esteroidais tenham provocado sintomas de asma, rinite, urticária. O uso de lisinato de cetoprofeno é contra-indicado durante o primeiro e o último trimestre de gestação, pois pode causar hipertensão pulmonar e toxicidade renal no feto, característica comum aos inibidores da síntese de prostaglandinas. Pode também levar ao aumento do tempo de sangramento das gestantes e fetos e conseqüentemente eventuais manifestações hemorrágicas no recém-nascido. Há risco de retardar o trabalho de parto. **Precauções e advertências: O uso de cetoprofeno em pacientes com asma brônquica ou com diáteses alérgicas pode provocar uma crise asmática. Em pacientes com função renal comprometida, a administração de cetoprofeno deve ser efetuada com particular cautela levando-se em consideração a eliminação essencialmente renal do fármaco.** Embora não tenha sido observada experimentalmente toxicidade embriofetal com cetoprofeno nas doses previstas para uso clínico, a administração em mulheres grávidas, durante a amamentação ou na infância não é recomendada. **Interações medicamentosas: Devido à elevada ligação de cetoprofeno com proteínas plasmáticas, é necessário reduzir a dosagem de anticoagulantes, fenitoínas ou sulfamidas quando administrados concomitantemente.** O uso com ácido acetilsalicílico reduz o nível sérico de cetoprofeno e aumenta o risco de distúrbios gastrintestinais. No caso da administração com lítio há aumento de seu nível sérico podendo levar à intoxicação. Foi observado aumento da toxicidade do metotrexato em decorrência da diminuição de seu "clearance" renal. A probenecida reduz as perdas de cetoprofeno e aumenta seu nível sérico. A metoclopramida reduz a biodisponibilidade do cetoprofeno e pode ocorrer uma pequena redução de sua absorção no uso simultâneo com hidróxidos de magnésio ou alumínio. **Reações adversas: Assim como com outros antiinflamatórios não-esteroidais, podem ocorrer distúrbios transitórios, no trato gastrintestinal, tais como gastralgia, náusea, vômito, diarréia e flatulência.** Excepcionalmente foram observadas hemorragia gastrintestinal, discinésia transitória, astenia, cefaléia, sensação de vertigem e exantema cutâneo. O produto pode ser tomado às refeições ou com leite, a fim de evitar possíveis distúrbios gastrintestinais. **Posologia:** ARTROSIL 160 mg: Uma cápsula duas vezes ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. ARTROSIL 320 mg: Uma cápsula ao dia durante ou após às refeições. A duração do tratamento deve ser a critério médico. SE PERSISTIREM OS SINTOMAS O MÉDICO DEVERÁ SER CONSULTADO. VENDA SOB PRESCRIÇÃO MÉDICA. MS – 1.0573.0128. MB_08 SAP 4057006.

Material técnico-científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos.

Referências Bibliográficas: 1) ALFANO, G. et al. Analgesia with paracetamol/tramadol vs. paracetamol/codeine in onca DaySurgery: a randomized open study. European Review for Medical and Pharmacological Sciences, v.15,p.205-21, 2011. 2) PERROT, S. et al. Efficacy and Tolerability of Paracetamol/Tramadol (325 mg/37.5 mg) Combination Treatment Compared with Tramadol (50 mg) Monotherapy in Patients with Subacute Low Back Pain: A Multicenter, Randomized, Double-Blind, Parallel-Group, 10-Day Treatment Study. Clin Ther, v. 28, n. 10, p. 1592-1606, 2006. 3) Bula do produto REVANGE: comprimidos revestidos. Farmacêutica Responsável: Gabriela Mallmann. Aché Laboratórios Farmacêuticos S.A. 4) MEDVE, R.A.; WANG, J. .; KARIM, R. Tramadol and acetaminophen tablets for dental pain. Anesth Prog, v.48, n.3, p.79-81 , 2001.

Contraindicações: hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada.

REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.

REVANGE®, cloridrato de tramadol e paracetamol. 37,5 MG + 325 MG comprimidos revestidos. USO ORAL. USO ADULTO. Indicações: dores moderadas a severas de caráter agudo, subagudo e crônico. **Contraindicações: hipersensibilidade ao tramadol, paracetamol ou a qualquer componente da fórmula ou aos opioides; intoxicações agudas pelo álcool, hipnóticos, analgésicos de ação central, opioides ou psicotrópicos; pacientes em tratamento com inibidores da monoaminoxidase (MAO) ou tratados com estes agentes nos últimos 14 dias.** Cuidados e advertências: convulsões foram relatadas em pacientes recebendo tramadol na dose recomendada. Relatos espontâneos pós-comercialização indicam que o risco de convulsões está aumentado com doses de tramadol acima das recomendadas. A administração de tramadol pode aumentar o risco de convulsão em pacientes tomando inibidores da MAO, neurolépticos ou outros fármacos que reduzem o limiar convulsivo. REVANGE® comprimido revestido não deve ser administrado à pacientes dependentes de opioides. O tramadol reinicia a dependência física em alguns pacientes previamente dependentes de outros opioides. REVANGE® comprimido revestido deve ser usado com cautela e em dose reduzida em pacientes recebendo depressores do SNC como álcool, opioides, agentes anestésicos, fenotiazinas, tranquilizantes ou sedativos hipnóticos. REVANGE® comprimido revestido deve ser usado com bastante cautela em pacientes sob tratamento com inibidores da monoaminoxidase pois os estudos em animais mostraram aumento da incidência de óbito com a administração combinada de inibidores da MAO e tramadol. Precauções e advertências: REVANGE® comprimido revestido não deve ser administrado em conjunto com outros produtos à base de tramadol ou paracetamol. REVANGE® comprimido revestido deve ser administrado com cautela em pacientes sob risco de depressão respiratória. REVANGE® comprimido revestido deve ser usado com cautela em pacientes com pressão intracraniana aumentada ou traumatismo craniano. Alterações da pupila (miose) provocadas pelo tramadol podem mascarar a existência, extensão ou curso da patologia intracraniana. Gravidez e lactação: uso na gravidez e lactação: REVANGE® comprimido revestido somente deverá ser utilizado durante a gravidez se o potencial benefício justificar o potencial risco para o feto. Interações medicamentosas: REVANGE® comprimido revestido não é recomendado como medicação pré-operatória obstétrica ou na analgesia pós-parto em lactantes, pois a segurança em lactentes e recém-nascidos não foi estudada. Reações adversas: efeitos sobre a capacidade de dirigir e operar máquinas: mesmo quando usado de acordo com as instruções, REVANGE® comprimido revestido pode afetar a habilidade mental ou física necessária para a realização de tarefas potencialmente perigosas como dirigir ou operar máquinas, especialmente ao início do tratamento, na mudança de outro produto para REVANGE® comprimido revestido e na administração concomitante de outras drogas de ação central e, em particular, do álcool. **REVANGE® é um medicamento. Durante seu uso, não dirija veículos ou opere máquinas, pois sua agilidade e atenção podem estar prejudicadas.** Os eventos adversos relatados com maior freqüência ocorreram no sistema nervoso central e gastrintestinal, sendo que os relatos mais comuns foram vertigem, náusea e sonolência. Posologia: a dose diária máxima de REVANGE® comprimido revestido é 1 a 2 comprimidos a cada 4 a 6 horas de acordo com a necessidade para alívio da dor, até o máximo de 8 comprimidos ao dia. A administração dos comprimidos pode ser feita independentemente das refeições. Nas condições dolorosas crônicas, o tratamento deve ser iniciado com 1 comprimido ao dia e aumentado em 1 comprimido a cada 3 dias, conforme a tolerância do paciente, até atingir a dose de 4 comprimidos ao dia. Depois disso, REVANGE® comprimido revestido pode ser administrado na dose de 1-2 comprimidos a cada 4-6 horas, até o máximo de 8 comprimidos ao dia. Nas condições dolorosas agudas, o tratamento pode ser iniciado com a dose terapêutica completa (1-2 comprimidos a cada 4-6 horas), até o máximo de 8 comprimidos ao dia. Pacientes com disfunção renal: em pacientes com "clearance" de creatinina inferior a 30 mL/min, recomenda-se aumentar o intervalo entre as administrações de REVANGE® comprimido revestido de forma a não exceder 2 comprimidos a cada 12 horas. VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA. Farmacêutica Responsável: Gabriela Mallmann CRF-SP 30.138. MS - 1.0573.0440. MB02 SAP 4389200.

CHEGOU

FOXIS
CELECOXIBE

Eficácia, segurança e preço acessível
no tratamento anti-inflamatório.[1-4]

- **Melhora significante** dos sinais e sintomas de osteoartrite.[6]
- **Eficaz** no tratamento de dor aguda.*[7]
- Inibidor da COX-2 **mais utilizado no mundo.**[5]

* Devido a entorse de tornozelo em 24 horas após o início do tratamento.

Referências bibliográficas: 1. SIMON, L.S. et al. Anti-inflammatory and upper gastrointestinal effects of celecoxib in rheumatoid arthritis: A randomized controlled trial. JAMA, v. 282, n. 20, 1999. **2.** ESSEX, M.N; BHADRA, P; SANDS, G.H. Efficacy and tolerability of celecoxib versus naproxen in patients with osteoarthritis of the knee: a randomized, double-blind, double-dummy trial. The journal of international medical research, v. 40, p. 1357-1370, 2012. **3.** LÉRIAS, J.R. Celecoxibe e rofecoxibe: eficácia e segurança dos inibidores selectivos da Cox-2 comparativamente aos AINEs não selectivos. Rev Port Clin Geral, v. 20, p. 47-64, 2004. **4.** Kairos Web Brasil. Disponível em: <http://brasil.kairosweb.com>. Acesso em: JUL/2017. **5.** SOLOMON, S.D. et al. Cardiovascular risk of celecoxib in 6 randomized placebo-controlled trials: The cross trial safety analysis. Circulation, v. 117, p. 2104-2113, 2008. **6.** BENSEN, W.G. et al. Treatment of osteoarthritis with celecoxib, a cyclooxygenase-2 inhibitor: A randomized controlled trial. Mayo ClinProc, v. 74, p. 1095-1105, 1999. **7.** CARDENAS-ESTRADA, E. et al. Efficacy and Safety of Celecoxib in the Treatment of Acute Pain due to Ankle Sprain in a Latin American and Middle Eastern Population. The Journal of International MedicalResearch, v. 37, p. 1937-1951, 2009.

FOXIS - celecoxibe. Cápsulas. 200 mg. USO ORAL. USO ADULTO. Indicações: Tratamento dos sinais e sintomas da osteoartrite e da artrite reumatoide; alívio dos sinais e sintomas da espondilite anquilosante; alívio da dor aguda (principalmente no pós-operatório de cirurgia ortopédica ou dental e em afecções musculoesqueléticas), alívio dos sintomas da dismenorreia primária e da lombalgia. **Contraindicações: Não deve ser usado por pacientes: que tenham tido crise de asma, urticária ou reações alérgicas após uso de ácido acetilsalicílico ou outros anti-inflamatórios; com doença hepática e/ou com insuficiência renal grave; que tenham dor relacionada à cirurgia de revascularização do miocárdio; com hipersensibilidade ao celecoxibe ou a qualquer componente da fórmula. Cuidados e advertências:** O uso de AINEs pode retardar ou inibir a ovulação, o que pode estar associado com a infertilidade reversível em algumas mulheres. Não deve ser usado por grávidas sem orientação e seguimento médico; especialmente durante o primeiro e segundo trimestres. O uso de celecoxibe durante a gravidez requer que se pesem os potenciais benefícios para a mãe e riscos para a criança. **Celecoxibe é um medicamento classificado na categoria C de risco de gravidez.** Embora reduza o risco de desenvolvimento de complicações gastrintestinais associadas ao uso de anti-inflamatórios, esse risco não está eliminado pelo uso de celecoxibe, sendo maior em maiores de 65 anos, consumo de bebidas alcoólicas ou com história anterior de perfuração, úlcera ou sangramento gastrintestinal. Celecoxibe deve ser usado com cautela em pacientes com: hipertensão, pois pode piorá-la; portadores de insuficiência renal, alterações da função hepática em idosos; portadores das alterações das enzimas metabolizadoras CYP2C9. Celecoxibe deve ser descontinuado ao aparecimento de rash cutâneo, lesões nas mucosas ou outros sinais de alergias. **Interação medicamentosa: anticoagulantes; anti-hipertensivos das classes dos inibidores da enzima conversora de angiotensina (ECA) e/ou antagonistas da angiotensina II diuréticos e betabloqueadores podem ter seu efeito reduzido; em pacientes idosos, com desidratação (incluindo aqueles em tratamento com diuréticos) ou com função renal comprometida, a coadministração de antiinflamatórios, incluindo os inibidores específicos da COX-2, com inibidores da ECA, pode resultar no comprometimento da função renal, incluindo possível insuficiência renal aguda; fluconazol pode aumentar os níveis sanguíneos de celecoxibe; lítio pode ter seu nível sanguíneo aumentado; medicamentos anti-inflamatórios podem aumentar o risco de toxicidade no rim associada à ciclosporina; a administração concomitante de dextrometorfano ou metoprolol com celecoxibe 200 mg duas vezes ao dia resultou em aumento de 2,6 vezes e 1,5 vezes das concentrações no sangue de dextrometorfano e metoprolol, respectivamente; lisinopril administrado concomitante com celecoxibe pode não controlar a pressão alta. Foxis 200 mg: Este produto contém o corante amarelo de TARTRAZINA que pode causar reações de natureza alérgica, entre as quais asma brônquica, especialmente em pessoas alérgicas ao ácido acetilsalicílico. Atenção: Este medicamento contém Açúcar, portanto, deve ser usado com cautela em portadores de Diabetes. Reações adversas: Comuns** (ocorre entre 1% e 10% dos pacientes): inflamação dos brônquios e seios da face, infecção do trato respiratório superior, infecção urinária, insônia, tontura, hipertensão e piora da hipertensão, tosse, vômito, dor abdominal, dispepsia, flatulência, prurido, rash, edema periférico. Incomuns (ocorre entre 0,1% e 1% dos pacientes): faringite; rinite, anemia, hipersensibilidade, ansiedade, hipertonia, sonolência, visão borrada, zumbido; palpitação, úlceras no estômago; doenças dentárias; aumento da quantidade de enzimas hepáticas, urticária, equimose, edema facial, doença semelhante à gripe, lesão. Infecção pela bactéria Helicobacter, pelo vírus Herpes zoster, infecções na pele, em feridas e gengiva, labirintite, infecção por bactéria, lipoma, distúrbio do soro, infarto cerebral, hemorragia conjuntival, depósitos no humor vítreo, hipoacusia, angina instável, insuficiência da valva aórtica; aterosclerose de artéria coronária; bradicardia sinusal, hipertrofia ventricular; trombose venosa profunda; hematoma; disfonia, sangramento da hemorroida; evacuações frequentes; ulceração da boca; estomatite; dermatite alérgica; cisto sinovial, noctúria, cisto ovariano, sintomas da menopausa; sensibilidade nas mamas; dismenorreia; aumento da quantidade de potássio e sódio no sangue, redução da testosterona no sangue; redução do hematócrito, aumento nos níveis de hemoglobina, fraturas, epicondilite, ruptura do tendão. Posologia: Celecoxibe deve ser engolido com ou sem alimentos. Para o tratamento de dor aguda e dismenorreia primária: 400 mg na primeira dose, seguidos de uma dose de 200 mg por via oral após 12 horas, seguido de 200 mg a cada 12 horas nos dias seguintes conforme necessário. Uso para o tratamento de dor crônica: menor dose diária eficaz durante o menor período possível. As doses sugeridas de celecoxibe para essas doenças são as seguintes: Osteoartrite e Espondilite anquilosante: 200 mg em dose única ou 100 mg duas vezes; Artrite reumatoide: 100 ou 200 mg duas vezes ao dia; Lombalgia: 200 mg ou 400 mg em dose única ou dividida em duas vezes de 100 mg ou 200 mg. SE PERSISTIREM OS SINTOMAS, O MÉDICO DEVERÁ SER CONSULTADO. **VENDA SOB PRESCRIÇÃO MÉDICA. SÓ PODE SER VENDIDO COM RETENÇÃO DA RECEITA. MS - 1.0573.0491. MB 02 VP_SAP 4591400_SAP 4585100. *Material técnico científico de distribuição exclusiva a profissionais de saúde habilitados à prescrição e/ou dispensação de medicamentos.**

CONTRAINDICAÇÕES: Não deve ser usado por pacientes: que tenham tido crise de asma, urticária ou reações alérgicas após uso de ácido acetilsalicílico ou outros anti-inflamatórios; com doença hepática e/ou com insuficiência renal grave; que tenham dor relacionada à cirurgia de revascularização do miocárdio; com hipersensibilidade ao celecoxibe ou a qualquer componente da fórmula. **INTERAÇÕES MEDICAMENTOSAS:** Anticoagulantes; anti-hipertensivos das classes dos inibidores da enzima conversora de angiotensina (ECA) e/ou antagonistas da angiotensina II diuréticos e betabloqueadores podem ter seu efeito reduzido; em pacientes idosos,) ou com função renal comprometida, a coadministração de anti-inflamatórios, incluindo os inibidores específicos da COX-2, com inibidores da ECA, pode resultar no comprometimento da função renal, incluindo possível insuficiência renal aguda; fluconazol pode aumentar os níveis sanguíneos de celecoxibe; medicamentos anti-inflamatórios podem aumentar o risco de toxicidade no rim associada à ciclosporina.

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Campanha RESPEITO PELA PRESCRIÇÃO E PELA ADESÃO AO TRATAMENTO
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